Dossier zur Nutzenbewertung gemäß § 35a SGB V

Epcoritamab (Tepkinly®)

AbbVie Deutschland GmbH & Co. KG

Modul 4 A

Anhang 4-G: Ergänzende Unterlagen

Erwachsene Patienten mit einem rezidivierenden oder refraktären follikulärem Lymphom

Stand: 09.07.2026

Contents

Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025 4

Table 1.1 Demographic and Baseline Disease characteristics 4
Table 1.2.1 Observation Duration: Efficacy 8
Table 1.2.2 Observation Duration: Safety 10
Table 1.3 Summary of first Post Treatment Anti-Lymphoma Therapies by Category 11
Table 2.1 Overall Survival 12
Figure 2.1 Kaplan-Meier Plot of Overall Survival 13
Table 2.1.S Overall Survival - Subgroup analysis 14
Table 2.2 Progression-free Survival per IRC Lugano 15
Figure 2.2 Kaplan-Meier Plot of Progression-free Survival per IRC Lugano 16
Table 2.2.S Progression-free Survival per IRC Lugano - Subgroup analysis 17
Table 2.3 Overall Response Rate Based on Lugano Criteria per IRC Assessment 18
Table 2.3.S Overall Response Rate Based on Lugano Criteria per IRC Assessment - Subgroup analysis 19
Table 2.4 Complete Response Rate Based on Lugano Criteria per IRC Assessment 20
Table 2.4.S Complete Response Rate Based on Lugano Criteria per IRC Assessment - Subgroup analysis 21
Table 2.5 Partial Response Rate Based on Lugano Criteria per IRC Assessment 22
Table 2.5.S Partial Response Rate Based on Lugano Criteria per IRC Assessment - Subgroup analysis 23
Table 2.6 Duration of response per IRC Lugano 24
Figure 2.6 Kaplan-Meier Plot of Duration of response per IRC Lugano 25
Table 2.6.S Duration of response per IRC Lugano - Subgroup analysis 26
Table 2.7 Duration of complete response per IRC Lugano 27
Figure 2.7 Kaplan-Meier Plot of Duration of complete response per IRC Lugano 28
Table 2.7.S Duration of complete response per IRC Lugano - Subgroup analysis 29
Table 2.8 Time to Next Anti-Lymphoma Treatment 30
Figure 2.8 Kaplan-Meier Plot of Time to Next Anti-Lymphoma Treatment 31
Table 2.8.S Time to Next Anti-Lymphoma Treatment - Subgroup analysis 32
Table 3.1.1 Completion rates of EQ-5D VAS Score 33
Table 3.1.2 Summary statistics and change from baseline of EQ-5D VAS Score 34
Figure 3.1.3 Graphical summary of change from baseline of EQ-5D VAS Score 35
Table 3.1.4 MMRM Analysis of change from baseline of EQ-5D VAS Score 36
Table 3.1.4.S MMRM Analysis of change from baseline of EQ-5D VAS Score - Subgroup analysis 37
Table 3.2.1 Completion rates of FACT-Lymphoma Total Score 38
Table 3.2.2 Summary statistics and change from baseline of FACT-Lymphoma Total Score 39
Figure 3.2.3 Graphical summary of change from baseline of FACT-Lymphoma Total Score 40
Table 3.2.4 MMRM Analysis of change from baseline of FACT-Lymphoma Total Score 41
Table 3.2.4.S MMRM Analysis of change from baseline of FACT-Lymphoma Total Score - Subgroup analysis 42
Table 3.3.1 Completion rates of FACT-G Total Score 43
Table 3.3.2 Summary statistics and change from baseline of FACT-G Total Score 44
Figure 3.3.3 Graphical summary of change from baseline of FACT-G Total Score 45
Table 3.3.4 MMRM Analysis of change from baseline of FACT-G Total Score 46
Table 3.3.4.S MMRM Analysis of change from baseline of FACT-G Total Score - Subgroup analysis 47
Table 3.4.1 Completion rates of Subscale Physical Well-Being 48
Table 3.4.2 Summary statistics and change from baseline of Subscale Physical Well-Being 49
Figure 3.4.3 Graphical summary of change from baseline of Subscale Physical Well-Being 50
Table 3.4.4 MMRM Analysis of change from baseline of Subscale Physical Well-Being 51
Table 3.4.4.S MMRM Analysis of change from baseline of Subscale Physical Well-Being - Subgroup analysis 52
Table 3.5.1 Completion rates of Subscale Social/Family Well Being 53
Table 3.5.2 Summary statistics and change from baseline of Subscale Social/Family Well Being 54
Figure 3.5.3 Graphical summary of change from baseline of Subscale Social/Family Well Being 55
Table 3.5.4 MMRM Analysis of change from baseline of Subscale Social/Family Well Being 56
Table 3.5.4.S MMRM Analysis of change from baseline of Subscale Social/Family Well Being - Subgroup analysis 57
Table 3.6.1 Completion rates of Subscale Emotional Well-Being 58
Table 3.6.2 Summary statistics and change from baseline of Subscale Emotional Well-Being 59
Figure 3.6.3 Graphical summary of change from baseline of Subscale Emotional Well-Being 60
Table 3.6.4 MMRM Analysis of change from baseline of Subscale Emotional Well-Being 61
Table 3.6.4.S MMRM Analysis of change from baseline of Subscale Emotional Well-Being - Subgroup analysis 62
Table 3.7.1 Completion rates of Subscale Functional Well-Being 63

Table 3.7.2 Summary statistics and change from baseline of Subscale Functional Well-Being 64
Figure 3.7.3 Graphical summary of change from baseline of Subscale Functional Well-Being 65
Table 3.7.4 MMRM Analysis of change from baseline of Subscale Functional Well-Being 66
Table 3.7.4.S MMRM Analysis of change from baseline of Subscale Functional Well-Being - Subgroup analysis 67
Table 3.8.1 Completion rates of Additional Lymphoma Score 68
Table 3.8.2 Summary statistics and change from baseline of Additional Lymphoma Score 69
Figure 3.8.3 Graphical summary of change from baseline of Additional Lymphoma Score 70
Table 3.8.4 MMRM Analysis of change from baseline of Additional Lymphoma Score 71
Table 3.8.4.S MMRM Analysis of change from baseline of Additional Lymphoma Score - Subgroup analysis 72
Table 3.9.1 Completion rates of FACT-Lymphoma Trial Outcome Index (TOI) 73
Table 3.9.2 Summary statistics and change from baseline of FACT-Lymphoma Trial Outcome Index (TOI) 74
Figure 3.9.3 Graphical summary of change from baseline of FACT-Lymphoma Trial Outcome Index (TOI) 75
Table 3.9.4 MMRM Analysis of change from baseline of FACT-Lymphoma Trial Outcome Index (TOI) 76
Table 3.9.4.S MMRM Analysis of change from baseline of FACT-Lymphoma Trial Outcome Index (TOI) - Subgroup analysis 77
Table 3.10.1 Completion rates of PGI-Change 78
Table 3.10.2 Summary statistics and change from baseline of PGI-Change 79
Figure 3.10.3 Graphical summary of change from baseline of PGI-Change 80
Table 3.10.4 MMRM Analysis of change from baseline of PGI-Change 81
Table 3.10.4.S MMRM Analysis of change from baseline of PGI-Change - Subgroup analysis 82
Table 3.11.1 Completion rates of PGI-Severity 83
Table 3.11.2 Summary statistics and change from baseline of PGI-Severity 84
Figure 3.11.3 Graphical summary of change from baseline of PGI-Severity 85
Table 3.11.4 MMRM Analysis of change from baseline of PGI-Severity 86
Table 3.11.4.S MMRM Analysis of change from baseline of PGI-Severity - Subgroup analysis 87
Table 4.1.1 Time to first Adverse Event 88
Figure 4.1.1 Kaplan-Meier Plot of Time to first Adverse Event 89
Table 4.1.1.S Time to first Adverse Event - Subgroup analysis 90
Table 4.1.2 Time to first Serious Adverse Event 91
Figure 4.1.2 Kaplan-Meier Plot of Time to first Serious Adverse Event 92
Table 4.1.2.S Time to first Serious Adverse Event - Subgroup analysis 93
Table 4.1.3 Time to first Severe Adverse Event 94
Figure 4.1.3 Kaplan-Meier Plot of Time to first Severe Adverse Event 95
Table 4.1.3.S Time to first Severe Adverse Event - Subgroup analysis 102
Table 4.1.4 Time to first Adverse Event leading to Death 103
Figure 4.1.4 Kaplan-Meier Plot of Time to first Adverse Event leading to Death 104
Table 4.1.4.S Time to first Adverse Event leading to Death - Subgroup analysis 105
Table 4.1.5 Time to first Adverse Event leading to Discontinuation of any Study Drug 106
Figure 4.1.5 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of any Study Drug 107
Table 4.1.5.S Time to first Adverse Event leading to Discontinuation of any Study Drug - Subgroup analysis 110
Table 4.1.6 Time to first Adverse Event leading to Discontinuation of Epcoritamab 111
Figure 4.1.6 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of Epcoritamab 112
Table 4.1.6.S Time to first Adverse Event leading to Discontinuation of Epcoritamab - Subgroup analysis 113
Table 4.1.7 Time to first Adverse Event leading to Discontinuation of Rituximab 114
Figure 4.1.7 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of Rituximab 115
Table 4.1.7.S Time to first Adverse Event leading to Discontinuation of Rituximab - Subgroup analysis 116
Table 4.1.8 Time to first Adverse Event leading to Discontinuation of Lenalidomide 117
Figure 4.1.8 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of Lenalidomide 118
Table 4.1.8.S Time to first Adverse Event leading to Discontinuation of Lenalidomide - Subgroup analysis 121
Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) 122
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) 209
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis 302
Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) 336
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) 346
Table 4.5.2.S Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis 356
Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) 361
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) 382
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis 407
Table 4.6.1 Incidence of Adverse Events leading to discontinuation of Epcoritamab by SOC and PT 415
Table 4.6.2 Incidence of Adverse Events leading to discontinuation of Rituximab by SOC and PT 417
Table 4.6.3 Incidence of Adverse Events leading to discontinuation of Lenalidomide by SOC and PT 418

Table 4.6.4 Incidence of Adverse Events leading to discontinuation of any Study Drug by SOC and PT 420

		EPCO 48mg + R2 (N=243)	R2 (N=245)
Sex, n (%)	Male	139 (57.2)	138 (56.3)
	Female	104 (42.8)	107 (43.7)
Ethnicity, n (%)	Hispanic or Latino	29 (12.2)	28 (11.5)
	Not Hispanic or Latino	209 (87.8)	215 (88.5)
	Missing	5	2
Race, n (%)	American Indian or Alaska Native	0 (0.0)	1 (0.4)
	Asian	63 (26.5)	54 (22.3)
	Black or African American	6 (2.5)	2 (0.8)
	White	168 (70.6)	184 (76.0)
	Multiple	1 (0.4)	1 (0.4)
	Missing	5	3
Age	n	243	245
	Mean (SD)	59.5 (11.65)	61.7 (11.83)
	Median	60.0	63.0
	Q1, Q3	50.0, 69.0	54.0, 71.0
	Min, Max	30.0, 84.0	24.0, 89.0
Age, n (%)	<65	155 (63.8)	139 (56.7)
	65-<75	68 (28.0)	71 (29.0)
	>=75	20 (8.2)	35 (14.3)
Baseline Height (cm)	n	243	244
	Mean (SD)	169.1 (9.30)	169.0 (9.83)
	Median	170.0	169.0
	Q1, Q3	163.0, 175.0	162.0, 175.5
	Min, Max	145.0, 198.0	148.0, 195.0
Baseline Weight (kg)	n	243	245
	Mean (SD)	75.3 (16.45)	77.2 (16.96)
	Median	74.1	76.5
	Q1, Q3	64.0, 86.0	65.9, 85.7
	Min, Max	42.0, 116.5	44.0, 144.5
Baseline Weight (kg), n (%)	<65 kg	67 (27.6)	52 (21.2)
	65-<85 kg	111 (45.7)	124 (50.6)
	>=85 kg	65 (26.7)	69 (28.2)
Baseline Body Mass Index (kg/m2)	n	243	244
	Mean (SD)	26.2 (4.55)	26.9 (4.69)
	Median	25.6	26.2
	Q1, Q3	23.0, 29.1	23.7, 29.3
	Min, Max	17.3, 39.8	19.0, 46.2
Baseline Body Mass Index (kg/m2), n (%)	<18.5	4 (1.6)	0 (0.0)
	18.5-<25	103 (42.4)	92 (37.7)
	25-<30	94 (38.7)	100 (41.0)
	>=30	42 (17.3)	52 (21.3)
Geographic Region 1, n (%)	US/Western Europe	58 (23.9)	60 (24.5)
	Rest of World	185 (76.1)	185 (75.5)
Geographic Region 2, n (%)	US/Canada/Puerto Rico	14 (5.8)	19 (7.8)
	Not US/Canada/Puerto Rico	229 (94.2)	226 (92.2)
Geographic Region 3, n (%)	North America/Western Europe	62 (25.5)	67 (27.3)

Percentages calculated on non-missing values.
N=Number of subjects in Intention-to-Treat Analysis Set, n=Number of subjects included in the analysis, SD=Standard Deviation, Q1=25th percentile, Q3=75th percentile, Min=Minimum, Max=Maximum.

		EPCO 48mg + R2 (N=243)	R2 (N=245)
Geographic Region 3, n (%)	Not North America/Western Europe	181 (74.5)	178 (72.7)
Geographic Region 4, n (%)	US	9 (3.7)	12 (4.9)
	Not US	234 (96.3)	233 (95.1)
Region from IRT, n (%)	US/Western Europe	58 (23.9)	60 (24.5)
	Rest of world	185 (76.1)	185 (75.5)
Baseline ECOG, n (%)	0	166 (68.3)	170 (69.4)
	1	72 (29.6)	68 (27.8)
	2	5 (2.1)	7 (2.9)
Time from Initial Diagnosis to Randomization (Years)	n	243	245
	Mean (SD)	6.0 (4.88)	6.7 (5.80)
	Median	4.5	5.3
	Q1, Q3	2.4, 8.2	2.7, 9.0
	Min, Max	0.2, 30.3	0.1, 43.0
Time since last line of therapy to randomization (months)	n	243	245
	Mean (SD)	32.5 (37.32)	35.3 (42.59)
	Median	21.5	17.7
	Q1, Q3	6.1, 40.7	5.2, 52.5
	Min, Max	0.2, 198.4	0.3, 229.5
Time since last line of therapy to randomization (months), n (%)	< 6 months	59 (24.3)	63 (25.7)
	>= 6 months	184 (75.7)	182 (74.3)
Follicular Lymphoma Grade, n (%)	1	61 (25.2)	43 (17.9)
	2	126 (52.1)	120 (50.0)
	3a	52 (21.5)	75 (31.3)
	Classical FL	3 (1.2)	2 (0.8)
	Missing	1	5
Ann Arbor staging, n (%)	Stage II	37 (15.2)	44 (18.0)
	Stage III	74 (30.5)	68 (27.8)
	Stage IV	132 (54.3)	133 (54.3)
FLIPI1 Category from initial diagnosis, n (%)	0 - 1	42 (17.4)	46 (19.2)
	2	68 (28.2)	73 (30.4)
	3 - 5	85 (35.3)	85 (35.4)
	Unknown	46 (19.1)	36 (15.0)
	Missing	2	5
FLIPI1 Category at Baseline, n (%)	0 - 1	63 (25.9)	56 (22.9)
	2	79 (32.5)	76 (31.0)
	3 - 5	100 (41.2)	113 (46.1)
	Unknown	1 (0.4)	0 (0.0)
FLIPI2 Category from initial diagnosis, n (%)	0	27 (11.3)	21 (8.9)
	1 - 2	85 (35.6)	91 (38.4)
	3 - 5	45 (18.8)	63 (26.6)
	Unknown	82 (34.3)	62 (26.2)
	Missing	4	8
FLIPI2 Category at Baseline, n (%)	0	23 (9.5)	24 (9.8)
	1 - 2	144 (59.3)	118 (48.2)
	3 - 5	51 (21.0)	85 (34.7)
	Unknown	25 (10.3)	18 (7.3)

Percentages calculated on non-missing values.
N=Number of subjects in Intention-to-Treat Analysis Set, n=Number of subjects included in the analysis, SD=Standard Deviation, Q1=25th percentile, Q3=75th percentile, Min=Minimum, Max=Maximum.

		EPCO 48mg + R2 (N=243)	R2 (N=245)
Presence of constitutional symptoms, n (%)	Any Constitutional Symptom	38 (15.6)	42 (17.1)
	Fever	3 (1.2)	2 (0.8)
	Weight Loss	11 (4.5)	13 (5.3)
	Night Sweat	32 (13.2)	35 (14.3)
Bulky Disease IRC - Cat 1, n (%)	<= 6cm	162 (68.1)	153 (64.6)
	> 6cm	76 (31.9)	84 (35.4)
	Missing	5	8
Bulky Disease IRC, n (%)	< 7cm	191 (80.3)	176 (74.3)
	>= 7cm	47 (19.7)	61 (25.7)
	Missing	5	8
Bone marrow involvement at baseline (investigator assessment), n (%)	Positive	70 (28.8)	68 (27.8)
	Negative	162 (66.7)	168 (68.6)
	Unknown	11 (4.5)	9 (3.7)
Presence of Extranodal Disease at screening, n (%)	Yes	101 (41.6)	105 (42.9)
	No	142 (58.4)	140 (57.1)
Baseline Renal Function, n (%)	Normal	124 (51.0)	131 (53.5)
	Mild Impairment	94 (38.7)	84 (34.3)
	Moderate Impairment	25 (10.3)	30 (12.2)
Baseline hepatic function per NCI, n (%)	Normal	217 (89.3)	215 (88.1)
	Mild Impairment	25 (10.3)	26 (10.7)
	Moderate Impairment	1 (0.4)	3 (1.2)
	Missing	0	1
Disease status from IRT, n (%)	2L	157 (64.6)	159 (64.9)
	3L+	86 (35.4)	86 (35.1)
	2L: progression of disease <= 2 years	63 (25.9)	63 (25.7)
	2L: progression of disease > 2 years	94 (38.7)	96 (39.2)
	3L+: >= 6 months	63 (25.9)	63 (25.7)
	3L+: < 6 months	23 (9.5)	23 (9.4)
Disease status, n (%)	2L	145 (59.7)	141 (57.6)
	3L+	98 (40.3)	104 (42.4)
	2L: PD <= 2 years from initiation of 1L	64 (26.3)	52 (21.5)
	2L: PD > 2 years from initiation of 1L	81 (33.3)	86 (35.5)
	3L+: >= 6 months since end of last therapy until randomization date	77 (31.7)	74 (30.6)
	3L+: < 6 months since end of last therapy until randomization date	21 (8.6)	30 (12.4)
Lactate Dehydrogenase at Baseline	n	242	244
	Mean (SD)	232.1 (87.25)	241.4 (167.09)
	Median	207.0	204.0
	Q1, Q3	175.0, 257.0	175.0, 256.5
	Min, Max	107.0, 670.0	91.0, 2284.1
Lactate Dehydrogenase at Baseline, n (%)	< 350	218 (90.1)	223 (91.4)
	>= 350	24 (9.9)	21 (8.6)

Percentages calculated on non-missing values.
N=Number of subjects in Intention-to-Treat Analysis Set, n=Number of subjects included in the analysis, SD=Standard Deviation, Q1=25th percentile, Q3=75th percentile, Min=Minimum, Max=Maximum.

		EPCO 48mg + R2 (N=243)	R2 (N=245)
Serum Hemoglobin at Baseline	n	243	245
	Mean (SD)	13.0 (1.69)	13.1 (1.62)
	Median	13.1	13.2
	Q1, Q3	12.1, 14.1	12.2, 14.3
	Min, Max	7.7, 17.6	8.0, 16.6
Serum Hemoglobin at Baseline, n (%)	< 12	52 (21.4)	54 (22.0)
	>= 12	191 (78.6)	191 (78.0)
AST at Baseline	n	243	244
	Mean (SD)	23.6 (9.50)	24.8 (12.07)
	Median	21.0	22.0
	Q1, Q3	17.0, 27.0	18.0, 27.5
	Min, Max	8.0, 67.0	7.4, 93.0
ALT at Baseline	n	243	245
	Mean (SD)	20.4 (11.36)	22.7 (14.27)
	Median	18.0	20.0
	Q1, Q3	13.0, 23.0	14.0, 26.0
	Min, Max	4.0, 76.0	6.0, 126.0
Bilirubin at Baseline	n	243	245
	Mean (SD)	10.0 (5.62)	9.7 (4.97)
	Median	8.9	8.6
	Q1, Q3	6.8, 11.6	6.5, 12.0
	Min, Max	3.0, 65.5	2.9, 38.7
Neutrophils at Baseline	n	243	245
	Mean (SD)	3.9 (1.83)	4.0 (1.80)
	Median	3.5	3.7
	Q1, Q3	2.7, 4.6	2.8, 5.0
	Min, Max	1.1, 12.6	1.0, 17.1
Lymphocytes at Baseline	n	242	244
	Mean (SD)	1.9 (3.59)	1.8 (2.60)
	Median	1.1	1.2
	Q1, Q3	0.8, 1.6	0.9, 1.6
	Min, Max	0.3, 36.8	0.1, 23.8
Platelets at Baseline	n	243	245
	Mean (SD)	192.0 (70.23)	200.5 (71.49)
	Median	181.0	199.0
	Q1, Q3	145.0, 236.0	153.0, 237.0
	Min, Max	39.0, 432.0	36.0, 498.0
Beta-2 Microglobulin at Baseline	n	236	239
	Mean (SD)	6.2 (8.87)	6.3 (9.73)
	Median	2.7	2.7
	Q1, Q3	2.1, 4.3	2.0, 4.1
	Min, Max	1.2, 54.4	1.1, 61.0
Creatinine Clearance at Baseline	n	243	245
	Mean (SD)	1.6 (0.49)	1.6 (0.51)
	Median	1.5	1.5
	Q1, Q3	1.3, 1.8	1.2, 1.9
	Min, Max	0.7, 3.2	0.6, 3.1

Percentages calculated on non-missing values.
N=Number of subjects in Intention-to-Treat Analysis Set, n=Number of subjects included in the analysis, SD=Standard Deviation, Q1=25th percentile, Q3=75th percentile, Min=Minimum, Max=Maximum.

Endpoint		EPCO 48mg + R2 (N=243)	R2 (N=245)
Observation duration for Overall Survival (months) *	n	243	245
	Mean (SD)	15.4 (5.80)	14.2 (6.18)
	Median	14.6	13.7
	Min, Max	0.4, 31.0	0.0, 29.7
Observation duration for PFS per IRC Lugano (months) *	n	243	245
	Mean (SD)	13.0 (5.71)	9.3 (5.65)
	Median	11.4	7.6
	Min, Max	0.0, 27.7	0.0, 28.1
Observation duration for DOR per IRC Lugano (months) *	n	231	194
	Mean (SD)	9.9 (5.38)	7.2 (5.15)
	Median	8.4	7.1
	Min, Max	0.0, 23.9	0.0, 24.9
Observation duration for DOCR per IRC Lugano (months) *	n	201	122
	Mean (SD)	9.1 (5.38)	7.2 (5.23)
	Median	7.7	7.2
	Min, Max	0.0, 23.9	0.0, 24.9
Observation duration for Time to Next Anti-Lymphoma Treatment (months) *	n	243	245
	Mean (SD)	14.9 (5.96)	12.1 (6.19)
	Median	14.1	12.0
	Min, Max	0.4, 31.0	0.0, 29.2
Observation duration for EQ-5D VAS Score (months) **	n	243	236
	Mean (SD)	13.1 (5.45)	10.3 (5.41)
	Median	12.1	10.2
	Min, Max	0.0, 29.2	0.0, 28.3
Observation duration for Additional Lymphoma Score (months) **	n	243	237
	Mean (SD)	13.4 (5.37)	11.5 (5.69)
	Median	12.3	11.1
	Min, Max	0.1, 29.2	0.0, 28.3
Observation duration for FACT-G Total Score (months) **	n	243	237
	Mean (SD)	13.4 (5.37)	11.5 (5.69)
	Median	12.3	11.1
	Min, Max	0.1, 29.2	0.0, 28.3
Observation duration for FACT-Lymphoma Total Score (months) **	n	243	237
	Mean (SD)	13.4 (5.37)	11.5 (5.69)
	Median	12.3	11.1
	Min, Max	0.1, 29.2	0.0, 28.3
Observation duration for FACT-Lymphoma Trial Outcome Index (TOI) (months) **	n	243	237
	Mean (SD)	13.4 (5.37)	11.5 (5.69)
	Median	12.3	11.1
	Min, Max	0.1, 29.2	0.0, 28.3
Observation duration for PGI-Change (months) **	n	240	229
	Mean (SD)	13.5 (5.16)	11.8 (5.38)
	Median	12.3	11.2
	Min, Max	1.1, 29.2	1.0, 28.3
Observation duration for PGI-Severity (months) **	n	243	236
	Mean (SD)	13.3 (5.34)	11.5 (5.69)

* Calculated as time from randomization until date of event/censoring.
** Calculated as time from randomization until date of last non-missing assessment.
N=Number of subjects in Intention-to-Treat Analysis Set, n=Number of subjects included in the analysis, SD=Standard Deviation, Min=Minimum, Max=Maximum.

Endpoint		EPCO 48mg + R2 (N=243)	R2 (N=245)
Observation duration for PGI-Severity (months) **	Median	12.2	11.1
	Min, Max	0.0, 29.2	0.0, 28.3

* Calculated as time from randomization until date of event/censoring.
** Calculated as time from randomization until date of last non-missing assessment.
N=Number of subjects in Intention-to-Treat Analysis Set, n=Number of subjects included in the analysis, SD=Standard Deviation, Min=Minimum, Max=Maximum.

Endpoint		EPCO 48mg + R2 (N=243)	R2 (N=238)
Observation duration for Safety (months)	n	243	238
	Mean (SD)	11.2 (3.03)	9.2 (3.37)
	Median	12.3	10.1
	Min, Max	0.4, 20.3	0.1, 14.3
Treatment duration of Epcoritamab (months)	n	243	–
	Mean (SD)	9.6 (2.78)	
	Median	10.4	
	Min, Max	0.3, 15.4	
Treatment duration of Lenalidomide (months)	n	243	236
	Mean (SD)	9.7 (3.13)	8.4 (3.34)
	Median	10.9	9.9
	Min, Max	0.3, 19.3	0.1, 13.3
Treatment duration of Rituximab (months)	n	243	238
	Mean (SD)	4.2 (1.24)	3.5 (0.95)
	Median	3.9	3.7
	Min, Max	0.3, 11.5	0.0, 5.3

Observation duration for safety calculated as time from first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Treatment duration calculated as time from first dose of study drug until date of last dose of study drug.
N=Number of subjects in Safety Analysis Set, n=Number of subjects included in the analysis, SD=Standard Deviation, Min=Minimum, Max=Maximum.

Table 1.3 Summary of first Post Treatment Anti-Lymphoma Therapies by Category

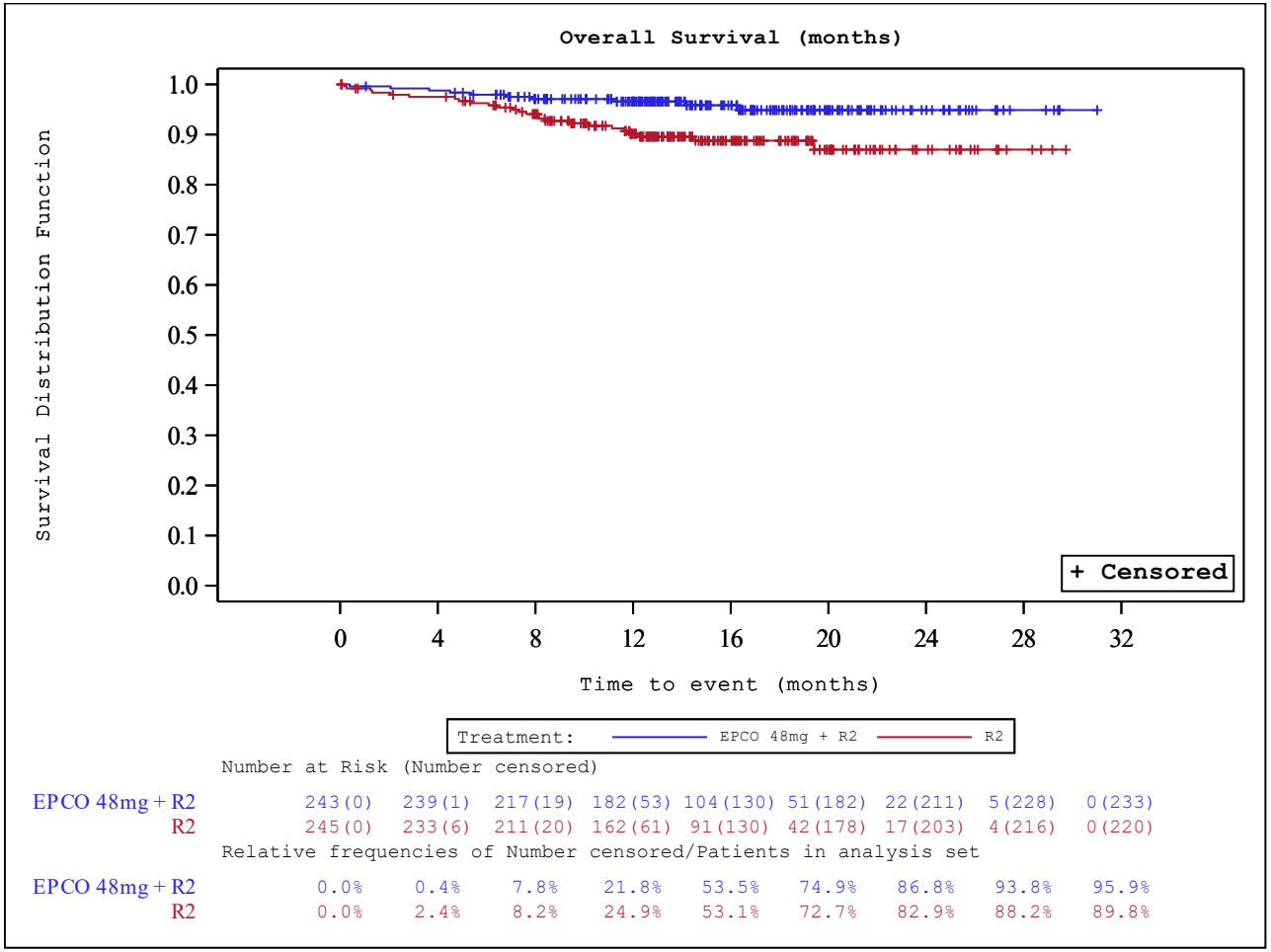
	EPCO 48mg + R2 (N=243)	R2 (N=245)
Any post treatment anti-lymphoma therapies	15 (6.2)	78 (31.8)
Systemic anti-lymphoma therapy	15 (6.2)	72 (29.4)
Anti-CD20 antibody	10 (4.1)	31 (12.7)
Anti-CD20 antibody containing chemotherapy	6 (2.5)	8 (3.3)
Alkyating Agents	5 (2.1)	15 (6.1)
Anthracyclines	2 (0.8)	4 (1.6)
Antimetabolite	3 (1.2)	8 (3.3)
CAR-T	0	12 (4.9)
Corticosteroids	3 (1.2)	5 (2.0)
Immunomodulatory	1 (0.4)	2 (0.8)
PI3K Inhibitors	1 (0.4)	1 (0.4)
Vinca Alkaloids	1 (0.4)	3 (1.2)
Radiotherapy	0	6 (2.4)

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 2.1 Overall Survival

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	10/243 (4.1)	25/245 (10.2)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
Median (95% CI)	NE (NE , NE)	NE (NE , NE)
75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
Stratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.38 (0.18, 0.80)	
p-value	0.0077	
Unstratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.38 (0.18, 0.79)	
p-value	0.0070	

25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
Stratified by disease history and region.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Figure 2.1 Kaplan-Meier Plot of Overall Survival



Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=245) n/ N (%)	R2 (N=245) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							0.8327
<65	5/ 155 (3.2)	NE (NE , NE)	10/ 139 (7.2)	NE (NE , NE)	0.43 (0.15, 1.26)	0.1123	
>=65	5/ 88 (5.7)	NE (NE , NE)	15/ 106 (14.2)	NE (NE , NE)	0.37 (0.14, 1.02)	0.0460	
Sex							0.4646
Male	6/ 139 (4.3)	NE (NE , NE)	11/ 138 (8.0)	NE (NE , NE)	0.50 (0.18, 1.34)	0.1582	
Female	4/ 104 (3.8)	NE (NE , NE)	14/ 107 (13.1)	NE (NE , NE)	0.28 (0.09, 0.86)	0.0177	
Disease Status 2L							0.8518
2L: progression of disease <= 2 years	3/ 63 (4.8)	NE (NE , NE)	9/ 63 (14.3)	NE (NE , NE)	0.31 (0.08, 1.14)	0.0617	
2L: progression of disease > 2 years	3/ 94 (3.2)	NE (NE , NE)	8/ 96 (8.3)	NE (NE , NE)	0.37 (0.10, 1.39)	0.1248	
Disease Status 3L+							
3L+: < 6 months	3/ 23 (13.0)		5/ 23 (21.7)				
3L+: >= 6 months	1/ 63 (1.6)		3/ 63 (4.8)				
Region							0.3359
US/Western Europe	2/ 58 (3.4)	NE (NE , NE)	2/ 60 (3.3)	NE (NE , NE)	0.93 (0.13, 6.64)	0.9459	
Rest of world	8/ 185 (4.3)	NE (NE , NE)	23/ 185 (12.4)	NE (NE , NE)	0.33 (0.15, 0.74)	0.0049	
Number of prior anti-lymphoma therapies							0.6229
2L	6/ 157 (3.8)	NE (NE , NE)	17/ 159 (10.7)	NE (NE , NE)	0.33 (0.13, 0.84)	0.0145	
3L+	4/ 86 (4.7)	NE (NE , NE)	8/ 86 (9.3)	NE (NE , NE)	0.48 (0.14, 1.60)	0.2209	

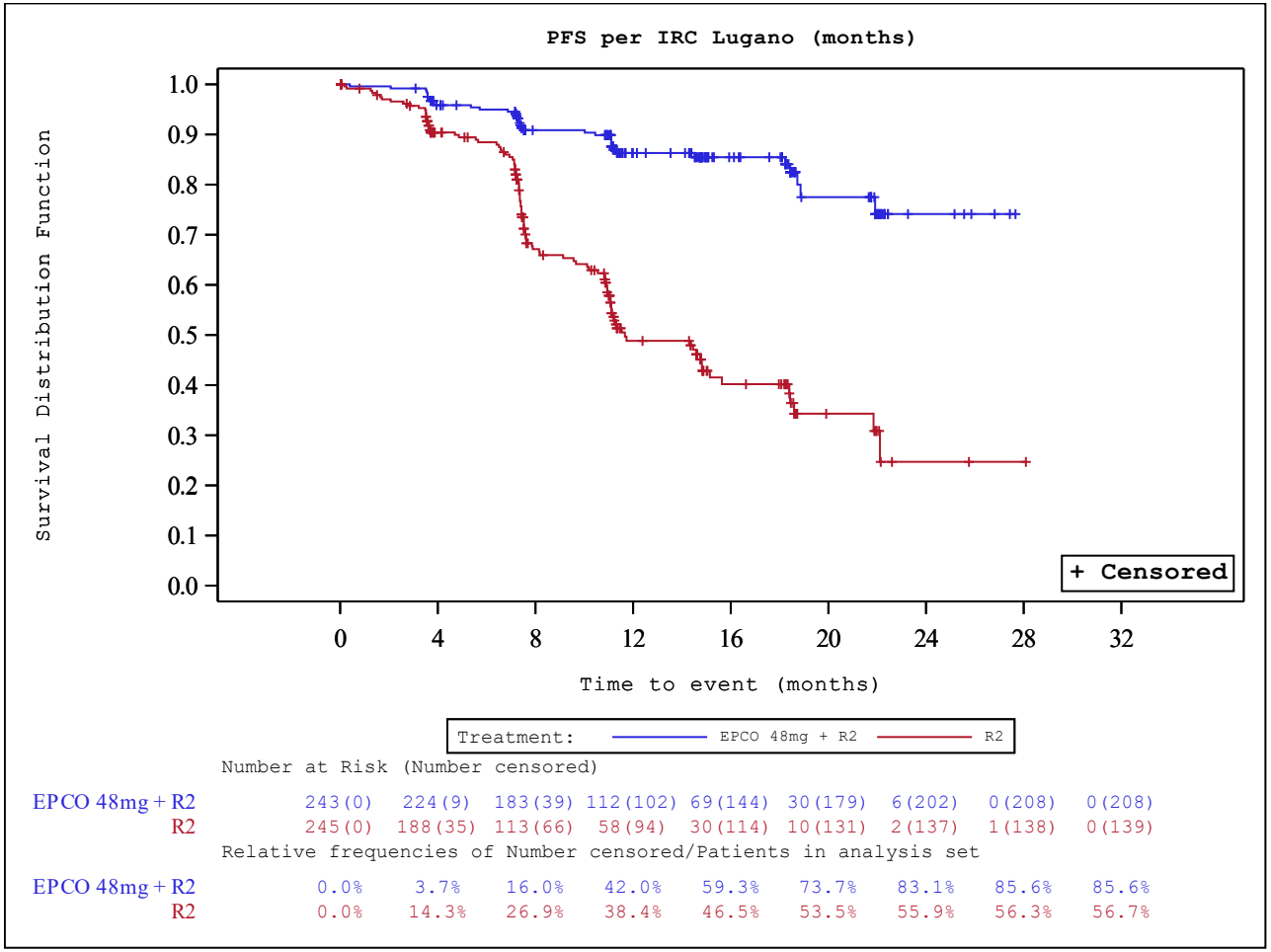
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable

Table 2.2 Progression-free Survival per IRC Lugano

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	35/243 (14.4)	106/245 (43.3)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	21.91 (18.73, NE)	7.43 (7.29, 7.62)
Median (95% CI)	NE (NE , NE)	11.66 (11.07, 15.15)
75%-ile (95% CI)	NE (NE , NE)	22.11 (21.85, NE)
Stratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.21 (0.14, 0.31)	
p-value	<.0001	
Unstratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.22 (0.15, 0.32)	
p-value	<.0001	

25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
Stratified by disease history and region.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Figure 2.2 Kaplan-Meier Plot of Progression-free Survival per IRC Lugano



Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 2.2.S Progression-free Survival per IRC Lugano - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=245) n/ N (%)	R2 (N=245) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.7266
<65	21/ 155 (13.5)	NE (NE , NE)	58/ 139 (41.7)	11.33 (10.94, 18.60)	0.20 (0.12, 0.33)	<.0001	
>=65	14/ 88 (15.9)	NE (18.86, NE)	48/ 106 (45.3)	14.46 (7.85, 18.40)	0.24 (0.13, 0.44)	<.0001	
Sex							0.3376
Male	23/ 139 (16.5)	NE (NE , NE)	54/ 138 (39.1)	14.46 (11.07, 21.85)	0.25 (0.16, 0.42)	<.0001	
Female	12/ 104 (11.5)	NE (NE , NE)	52/ 107 (48.6)	11.27 (9.66, 15.15)	0.17 (0.09, 0.31)	<.0001	
Disease Status 2L							0.9688
2L: progression of disease <= 2 years	14/ 63 (22.2)	NE (18.23, NE)	32/ 63 (50.8)	7.85 (7.33, 11.10)	0.22 (0.12, 0.42)	<.0001	
2L: progression of disease > 2 years	11/ 94 (11.7)	NE (21.91, NE)	36/ 96 (37.5)	18.43 (11.73, 21.85)	0.21 (0.11, 0.42)	<.0001	
Disease Status 3L+							0.7273
3L+: < 6 months	4/ 23 (17.4)	NE (NE , NE)	15/ 23 (65.2)	11.07 (6.41, 11.53)	0.17 (0.06, 0.54)	0.0007	
3L+: >= 6 months	6/ 63 (9.5)	NE (NE , NE)	23/ 63 (36.5)	15.15 (10.94, NE)	0.19 (0.08, 0.46)	<.0001	
Region							0.6853
US/Western Europe	5/ 58 (8.6)	NE (NE , NE)	18/ 60 (30.0)	NE (11.10, NE)	0.18 (0.07, 0.49)	0.0002	
Rest of world	30/ 185 (16.2)	NE (NE , NE)	88/ 185 (47.6)	11.24 (10.87, 14.82)	0.22 (0.15, 0.34)	<.0001	
Number of prior anti-lymphoma therapies							0.5697
2L	25/ 157 (15.9)	NE (NE , NE)	68/ 159 (42.8)	11.73 (10.87, 18.43)	0.23 (0.15, 0.37)	<.0001	
3L+	10/ 86 (11.6)	NE (NE , NE)	38/ 86 (44.2)	11.33 (10.91, 18.40)	0.18 (0.09, 0.37)	<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable

Table 2.3 Overall Response Rate Based on Lugano Criteria per IRC Assessment

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	231/243 (95.1)	194/245 (79.2)
Stratified Analysis EPCO 48mg + R2 vs. R2		
Relative Risk (95% CI)	1.20 (1.12, 1.29)	
p-value	<.0001	
Odds Ratio (95% CI)	5.40 (2.76, 10.58)	
p-value	<.0001	
Risk Difference (95% CI)	15.99 (10.29, 21.69)	
p-value	<.0001	

RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. The 95% CI and p-value is calculated on a normal approximation.
OR, RR > 1 as well as RD > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
Stratified by disease history and region.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Table 2.3.S Overall Response Rate Based on Lugano Criteria per IRC Assessment - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	R2 (N=245) n/ N (%)	EPCO 48mg + R2 vs. R2 Relative Risk (95% CI)	p-Value	Interaction p-Value
Age (years)					0.6344
<65	148/ 155 (95.5)	109/ 139 (78.4)	1.22 (1.11, 1.34)	<.0001	
>=65	83/ 88 (94.3)	85/ 106 (80.2)	1.18 (1.06, 1.31)	0.0031	
Sex					0.3820
Male	133/ 139 (95.7)	107/ 138 (77.5)	1.23 (1.12, 1.36)	<.0001	
Female	98/ 104 (94.2)	87/ 107 (81.3)	1.16 (1.05, 1.28)	0.0048	
Disease Status 2L					0.1588
2L: progression of disease <= 2 years	59/ 63 (93.7)	44/ 63 (69.8)	1.34 (1.13, 1.60)	0.0010	
2L: progression of disease > 2 years	91/ 94 (96.8)	80/ 96 (83.3)	1.16 (1.05, 1.28)	0.0024	
Disease Status 3L+					0.3073
3L+: < 6 months	20/ 23 (87.0)	15/ 23 (65.2)	1.33 (0.95, 1.87)	0.0951	
3L+: >= 6 months	61/ 63 (96.8)	55/ 63 (87.3)	1.11 (1.00, 1.23)	0.0516	
Region					0.7016
US/Western Europe	57/ 58 (98.3)	48/ 60 (80.0)	1.23 (1.08, 1.40)	0.0021	
Rest of world	174/ 185 (94.1)	146/ 185 (78.9)	1.19 (1.10, 1.29)	<.0001	
Number of prior anti-lymphoma therapies					0.4395
2L	150/ 157 (95.5)	124/ 159 (78.0)	1.23 (1.12, 1.34)	<.0001	
3L+	81/ 86 (94.2)	70/ 86 (81.4)	1.16 (1.03, 1.30)	0.0120	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR > 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 2.4 Complete Response Rate Based on Lugano Criteria per IRC Assessment

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	201/243 (82.7)	122/245 (49.8)
Stratified Analysis EPCO 48mg + R2 vs. R2		
Relative Risk (95% CI)	1.67 (1.45, 1.91)	
p-value	<.0001	
Odds Ratio (95% CI)	5.16 (3.35, 7.93)	
p-value	<.0001	
Risk Difference (95% CI)	33.07 (25.33, 40.80)	
p-value	<.0001	

RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. The 95% CI and p-value is calculated on a normal approximation.
OR, RR > 1 as well as RD > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
Stratified by disease history and region.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Table 2.4.S Complete Response Rate Based on Lugano Criteria per IRC Assessment - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	R2 (N=245) n/ N (%)	EPCO 48mg + R2 vs. R2 Relative Risk (95% CI)	p-Value	Interaction p-Value
Age (years)					0.2876
<65	130/ 155 (83.9)	75/ 139 (54.0)	1.55 (1.31, 1.84)	<.0001	
>=65	71/ 88 (80.7)	47/ 106 (44.3)	1.82 (1.44, 2.31)	<.0001	
Sex					0.9602
Male	120/ 139 (86.3)	72/ 138 (52.2)	1.65 (1.39, 1.97)	<.0001	
Female	81/ 104 (77.9)	50/ 107 (46.7)	1.67 (1.33, 2.09)	<.0001	
Disease Status 2L					0.0375
2L: progression of disease <= 2 years	51/ 63 (81.0)	24/ 63 (38.1)	2.13 (1.52, 2.98)	<.0001	
2L: progression of disease > 2 years	82/ 94 (87.2)	59/ 96 (61.5)	1.42 (1.19, 1.69)	<.0001	
Disease Status 3L+					0.4926
3L+: < 6 months	15/ 23 (65.2)	7/ 23 (30.4)	2.14 (1.08, 4.26)	0.0295	
3L+: >= 6 months	53/ 63 (84.1)	32/ 63 (50.8)	1.66 (1.27, 2.16)	0.0002	
Region					0.8108
US/Western Europe	50/ 58 (86.2)	32/ 60 (53.3)	1.62 (1.25, 2.09)	0.0003	
Rest of world	151/ 185 (81.6)	90/ 185 (48.6)	1.68 (1.43, 1.97)	<.0001	
Number of prior anti-lymphoma therapies					0.6431
2L	133/ 157 (84.7)	83/ 159 (52.2)	1.62 (1.38, 1.91)	<.0001	
3L+	68/ 86 (79.1)	39/ 86 (45.3)	1.74 (1.35, 2.25)	<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR > 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; NE=Not estimable.

Table 2.5 Partial Response Rate Based on Lugano Criteria per IRC Assessment

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	30/243 (12.3)	72/245 (29.4)
Stratified Analysis EPCO 48mg + R2 vs. R2		
Relative Risk (95% CI)	0.42 (0.29, 0.62)	
p-value	<.0001	
Odds Ratio (95% CI)	0.33 (0.21, 0.53)	
p-value	<.0001	
Risk Difference (95% CI)	-17.08 (-24.07, -10.09)	
p-value	<.0001	

RR, OR, RD estimated using Mantel-Haenszel method or logit method in case of zero events. The 95% CI and p-value is calculated on a normal approximation.
OR, RR > 1 as well as RD > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
Stratified by disease history and region.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Table 2.5.S Partial Response Rate Based on Lugano Criteria per IRC Assessment - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	R2 (N=245) n/ N (%)	EPCO 48mg + R2 vs. R2 Relative Risk (95% CI)	p-Value	Interaction p-Value
Age (years)					0.5797
<65	18/ 155 (11.6)	34/ 139 (24.5)	0.47 (0.28, 0.80)	0.0053	
>=65	12/ 88 (13.6)	38/ 106 (35.8)	0.38 (0.21, 0.68)	0.0012	
Sex					0.5320
Male	13/ 139 (9.4)	35/ 138 (25.4)	0.37 (0.20, 0.67)	0.0009	
Female	17/ 104 (16.3)	37/ 107 (34.6)	0.47 (0.28, 0.78)	0.0038	
Disease Status 2L					0.8651
2L: progression of disease <= 2 years	8/ 63 (12.7)	20/ 63 (31.7)	0.40 (0.19, 0.84)	0.0155	
2L: progression of disease > 2 years	9/ 94 (9.6)	21/ 96 (21.9)	0.44 (0.21, 0.91)	0.0260	
Disease Status 3L+					0.3384
3L+: < 6 months	5/ 23 (21.7)	8/ 23 (34.8)	0.63 (0.24, 1.63)	0.3354	
3L+: >= 6 months	8/ 63 (12.7)	23/ 63 (36.5)	0.35 (0.17, 0.72)	0.0043	
Region					0.8367
US/Western Europe	7/ 58 (12.1)	16/ 60 (26.7)	0.45 (0.20, 1.02)	0.0555	
Rest of world	23/ 185 (12.4)	56/ 185 (30.3)	0.41 (0.26, 0.64)	<.0001	
Number of prior anti-lymphoma therapies					0.9973
2L	17/ 157 (10.8)	41/ 159 (25.8)	0.42 (0.25, 0.71)	0.0011	
3L+	13/ 86 (15.1)	31/ 86 (36.0)	0.42 (0.24, 0.74)	0.0030	

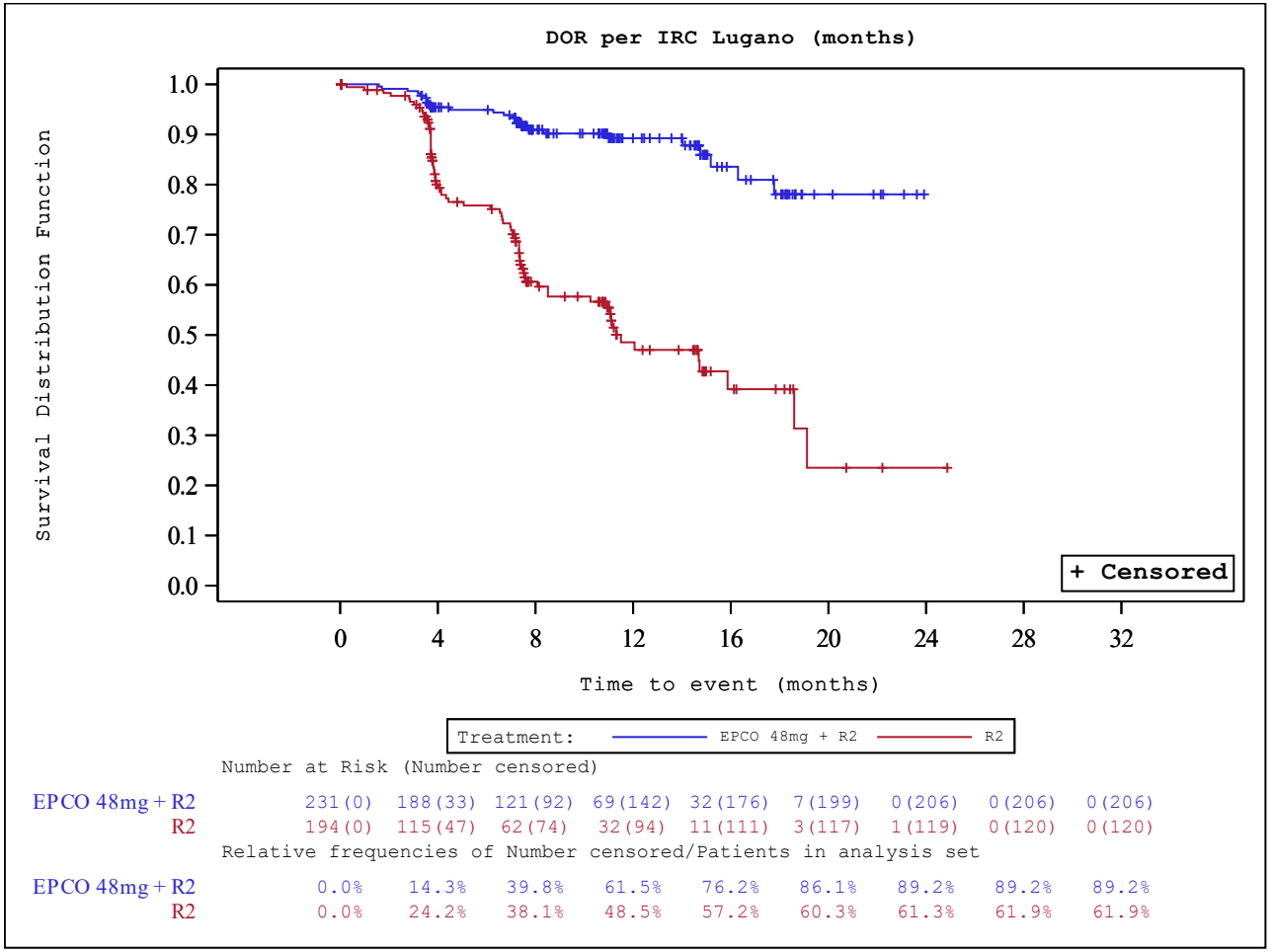
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR > 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is calculated from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; NE=Not estimable.

Table 2.6 Duration of response per IRC Lugano

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	25/231 (10.8)	74/194 (38.1)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	NE (15.18, NE)	6.54 (3.91, 7.33)
Median (95% CI)	NE (NE , NE)	11.50 (8.51, 18.60)
75%-ile (95% CI)	NE (NE , NE)	19.12 (18.60, NE)
Stratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.19 (0.12, 0.30)	
p-value	<.0001	
Unstratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.20 (0.12, 0.31)	
p-value	<.0001	

25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model
Hazard ratios > 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
Stratified by disease history and region.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Figure 2.6 Kaplan-Meier Plot of Duration of response per IRC Lugano



Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Table 2.6.S Duration of response per IRC Lugano - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=231) n/ N (%)	EPCO 48mg + R2 (N=231) Median (95%-CI)	R2 (N=194) n/ N (%)	R2 (N=194) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.8551
<65	15/ 148 (10.1)	NE (NE , NE)	40/ 109 (36.7)	12.06 (7.52, 19.12)	0.19 (0.10, 0.34)	<.0001	
>=65	10/ 83 (12.0)	NE (16.30, NE)	34/ 85 (40.0)	11.30 (8.51, NE)	0.21 (0.10, 0.43)	<.0001	
Sex							0.2445
Male	17/ 133 (12.8)	NE (NE , NE)	36/ 107 (33.6)	15.87 (10.25, 19.12)	0.24 (0.14, 0.44)	<.0001	
Female	8/ 98 (8.2)	NE (NE , NE)	38/ 87 (43.7)	11.14 (7.33, 14.72)	0.14 (0.06, 0.29)	<.0001	
Disease Status 2L							0.8659
2L: progression of disease <= 2 years	11/ 59 (18.6)	NE (NE , NE)	21/ 44 (47.7)	7.06 (3.91, 12.06)	0.22 (0.10, 0.45)	<.0001	
2L: progression of disease > 2 years	9/ 91 (9.9)	NE (NE , NE)	26/ 80 (32.5)	14.69 (11.07, NE)	0.23 (0.11, 0.49)	<.0001	
Disease Status 3L+							0.4593
3L+: < 6 months	1/ 20 (5.0)	NE (NE , NE)	8/ 15 (53.3)	8.51 (3.81, 14.72)	0.06 (0.01, 0.51)	0.0007	
3L+: >= 6 months	4/ 61 (6.6)	NE (16.30, NE)	19/ 55 (34.5)	18.60 (7.33, NE)	0.15 (0.05, 0.43)	<.0001	
Region							0.7683
US/Western Europe	4/ 57 (7.0)	NE (NE , NE)	14/ 48 (29.2)	NE (10.25, NE)	0.17 (0.06, 0.53)	0.0005	
Rest of world	21/ 174 (12.1)	NE (NE , NE)	60/ 146 (41.1)	11.10 (7.43, 14.72)	0.20 (0.12, 0.33)	<.0001	
Number of prior anti-lymphoma therapies							0.1993
2L	20/ 150 (13.3)	NE (NE , NE)	47/ 124 (37.9)	11.14 (8.08, 19.12)	0.24 (0.14, 0.41)	<.0001	
3L+	5/ 81 (6.2)	NE (NE , NE)	27/ 70 (38.6)	11.50 (7.33, NE)	0.12 (0.04, 0.30)	<.0001	

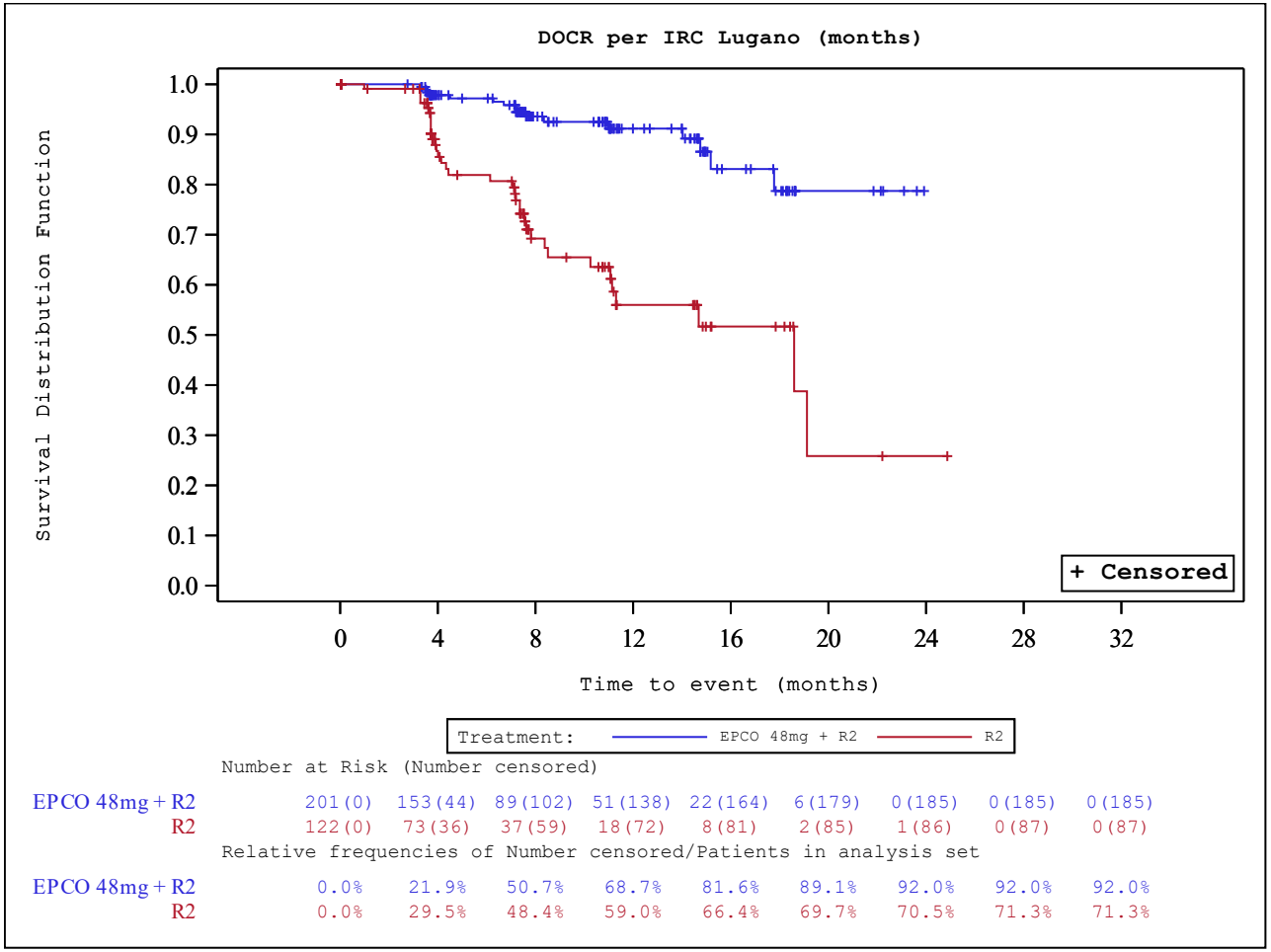
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using unstratified Cox proportional hazards model
Hazard ratios > 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 2.7 Duration of complete response per IRC Lugano

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	16/201 (8.0)	35/122 (28.7)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	NE (15.18, NE)	7.36 (4.34, 10.25)
Median (95% CI)	NE (NE , NE)	18.60 (11.07, NE)
75%-ile (95% CI)	NE (NE , NE)	NE (18.60, NE)
Stratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.21 (0.11, 0.39)	
p-value	<.0001	
Unstratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.21 (0.12, 0.38)	
p-value	<.0001	

25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model
Hazard ratios > 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
Stratified by disease history and region.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Figure 2.7 Kaplan-Meier Plot of Duration of complete response per IRC Lugano



Number at Risk (Number censored)

EPCO 48mg + R2	201 (0)	153 (44)	89 (102)	51 (138)	22 (164)	6 (179)	0 (185)	0 (185)	0 (185)
R2	122 (0)	73 (36)	37 (59)	18 (72)	8 (81)	2 (85)	1 (86)	0 (87)	0 (87)

Relative frequencies of Number censored/Patients in analysis set

EPCO 48mg + R2	0.0%	21.9%	50.7%	68.7%	81.6%	89.1%	92.0%	92.0%	92.0%
R2	0.0%	29.5%	48.4%	59.0%	66.4%	69.7%	70.5%	71.3%	71.3%

Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Table 2.7.S Duration of complete response per IRC Lugano - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=201) n/ N (%)	EPCO 48mg + R2 (N=201) Median (95%-CI)	R2 (N=122) n/ N (%)	R2 (N=122) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.9707
<65	10/ 130 (7.7)	NE (NE , NE)	20/ 75 (26.7)	18.60 (8.38, NE)	0.21 (0.10, 0.45)	<.0001	
>=65	6/ 71 (8.5)	NE (15.18, NE)	15/ 47 (31.9)	14.69 (10.25, NE)	0.21 (0.08, 0.54)	0.0004	
Sex							0.4312
Male	12/ 120 (10.0)	NE (NE , NE)	19/ 72 (26.4)	18.60 (8.51, 19.12)	0.25 (0.12, 0.51)	<.0001	
Female	4/ 81 (4.9)	NE (15.18, NE)	16/ 50 (32.0)	14.69 (7.82, NE)	0.14 (0.05, 0.42)	<.0001	
Disease Status 2L							0.3289
2L: progression of disease <= 2 years	9/ 51 (17.6)	NE (14.03, NE)	9/ 24 (37.5)	8.38 (4.34, NE)	0.34 (0.14, 0.88)	0.0197	
2L: progression of disease > 2 years	5/ 82 (6.1)	NE (17.77, NE)	17/ 59 (28.8)	14.69 (10.25, NE)	0.15 (0.06, 0.41)	<.0001	
Disease Status 3L+							
3L+: < 6 months	0/ 15 (0.0)		2/ 7 (28.6)				
3L+: >= 6 months	2/ 53 (3.8)		7/ 32 (21.9)				
Region							0.5527
US/Western Europe	2/ 50 (4.0)	NE (NE , NE)	8/ 32 (25.0)	NE (10.25, NE)	0.14 (0.03, 0.65)	0.0032	
Rest of world	14/ 151 (9.3)	NE (NE , NE)	27/ 90 (30.0)	14.69 (8.51, 19.12)	0.23 (0.12, 0.43)	<.0001	
Number of prior anti-lymphoma therapies							0.3450
2L	14/ 133 (10.5)	NE (NE , NE)	26/ 83 (31.3)	14.69 (8.38, NE)	0.24 (0.13, 0.47)	<.0001	
3L+	2/ 68 (2.9)	NE (NE , NE)	9/ 39 (23.1)	18.60 (8.51, NE)	0.11 (0.02, 0.53)	0.0009	

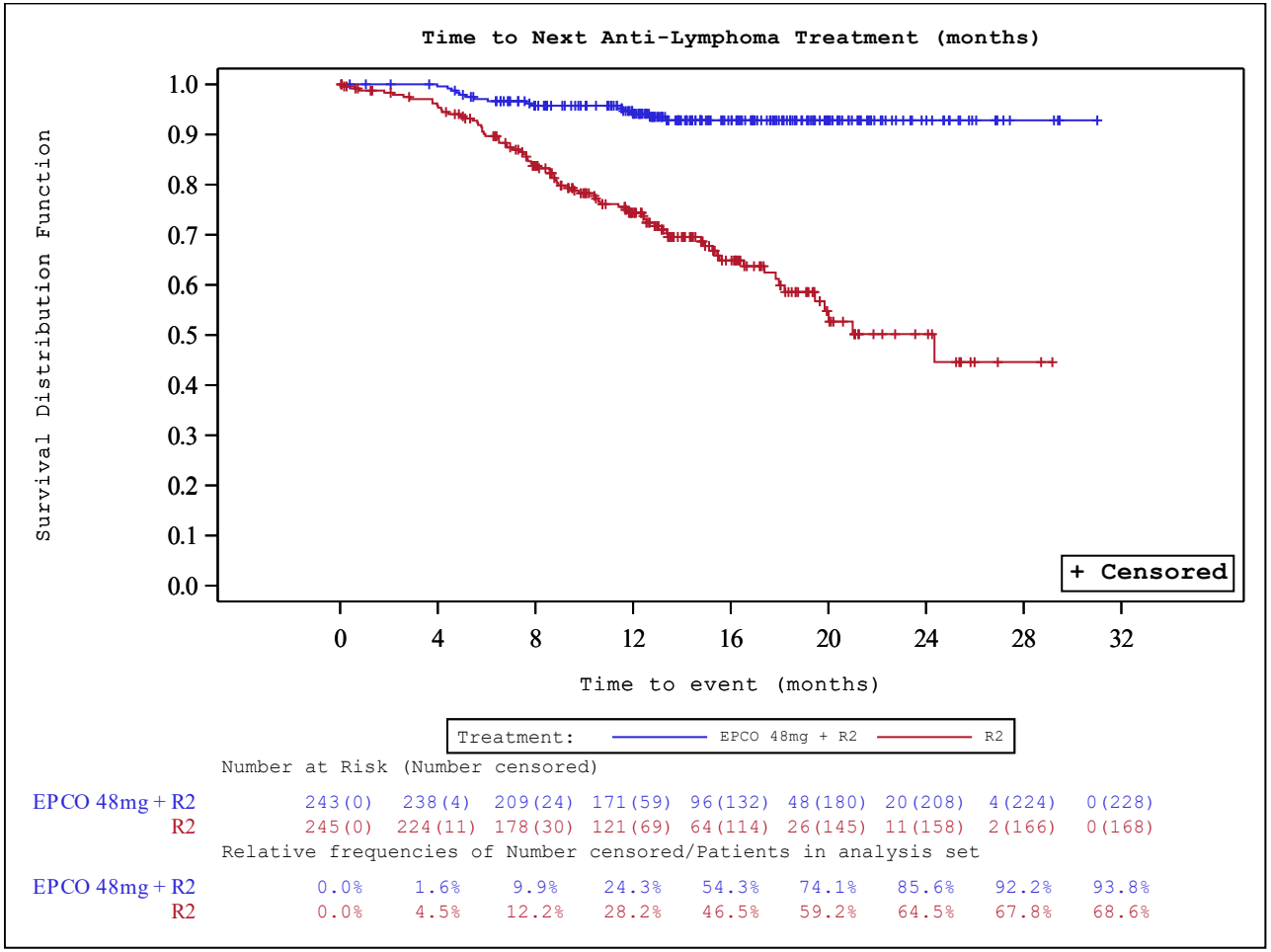
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using unstratified Cox proportional hazards model
Hazard ratios > 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable

Table 2.8 Time to Next Anti-Lymphoma Treatment

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	15/243 (6.2)	77/245 (31.4)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	NE (NE , NE)	11.70 (8.84, 14.78)
Median (95% CI)	NE (NE , NE)	24.34 (18.20, NE)
75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
Stratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.15 (0.09, 0.27)	
p-value	<.0001	
Unstratified Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.16 (0.09, 0.27)	
p-value	<.0001	

25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
Stratified by disease history and region.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Figure 2.8 Kaplan-Meier Plot of Time to Next Anti-Lymphoma Treatment



Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Table 2.8.S Time to Next Anti-Lymphoma Treatment - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=245) n/ N (%)	R2 (N=245) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.9489
<65	10/ 155 (6.5)	NE (NE , NE)	46/ 139 (33.1)	20.99 (16.53, NE)	0.16 (0.08, 0.31)	<.0001	
>=65	5/ 88 (5.7)	NE (NE , NE)	31/ 106 (29.2)	NE (19.45, NE)	0.15 (0.06, 0.40)	<.0001	
Sex							0.8128
Male	9/ 139 (6.5)	NE (NE , NE)	41/ 138 (29.7)	24.34 (19.84, NE)	0.17 (0.08, 0.35)	<.0001	
Female	6/ 104 (5.8)	NE (NE , NE)	36/ 107 (33.6)	18.20 (16.53, NE)	0.14 (0.06, 0.34)	<.0001	
Disease Status 2L							0.1522
2L: progression of disease <= 2 years	8/ 63 (12.7)	NE (NE , NE)	25/ 63 (39.7)	19.84 (10.58, NE)	0.24 (0.11, 0.53)	0.0001	
2L: progression of disease > 2 years	3/ 94 (3.2)	NE (NE , NE)	28/ 96 (29.2)	NE (16.53, NE)	0.09 (0.03, 0.28)	<.0001	
Disease Status 3L+							0.1878
3L+: < 6 months	3/ 23 (13.0)	NE (NE , NE)	8/ 23 (34.8)	17.38 (8.61, NE)	0.31 (0.08, 1.19)	0.0719	
3L+: >= 6 months	1/ 63 (1.6)	NE (NE , NE)	16/ 63 (25.4)	NE (18.20, NE)	0.05 (0.01, 0.40)	<.0001	
Region							0.2390
US/Western Europe	2/ 58 (3.4)	NE (NE , NE)	21/ 60 (35.0)	20.01 (15.54, NE)	0.07 (0.02, 0.32)	<.0001	
Rest of world	13/ 185 (7.0)	NE (NE , NE)	56/ 185 (30.3)	24.34 (18.20, NE)	0.19 (0.10, 0.35)	<.0001	
Number of prior anti-lymphoma therapies							0.8277
2L	11/ 157 (7.0)	NE (NE , NE)	53/ 159 (33.3)	24.34 (17.84, NE)	0.16 (0.09, 0.31)	<.0001	
3L+	4/ 86 (4.7)	NE (NE , NE)	24/ 86 (27.9)	NE (17.38, NE)	0.14 (0.05, 0.41)	<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable

Table 3.1.1 Completion rates of EQ-5D VAS Score

	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	217/ 243	89.3%	205/ 245	83.7%
Cycle 2 Day 1	183/ 243	75.3%	198/ 244	81.1%
Cycle 3 Day 1	174/ 241	72.2%	200/ 236	84.7%
Cycle 4 Day 1	194/ 240	80.8%	194/ 234	82.9%
Cycle 5 Day 1	195/ 240	81.3%	184/ 233	79.0%
Cycle 6 Day 1	194/ 239	81.2%	162/ 233	69.5%
Cycle 7 Day 1	196/ 236	83.1%	165/ 229	72.1%
Cycle 8 Day 1	193/ 234	82.5%	156/ 226	69.0%
Cycle 9 Day 1	178/ 227	78.4%	128/ 220	58.2%
Cycle 10 Day 1	170/ 221	76.9%	119/ 214	55.6%
Cycle 11 Day 1	152/ 209	72.7%	103/ 199	51.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	179/ 243	73.7%	174/ 245	71.0%
Follow up 1	92		66	
Follow up 2	32		15	
Follow up 3	34		21	
Follow up 4	19		11	
Follow up 5	5		2	
Follow up 6	3		1	

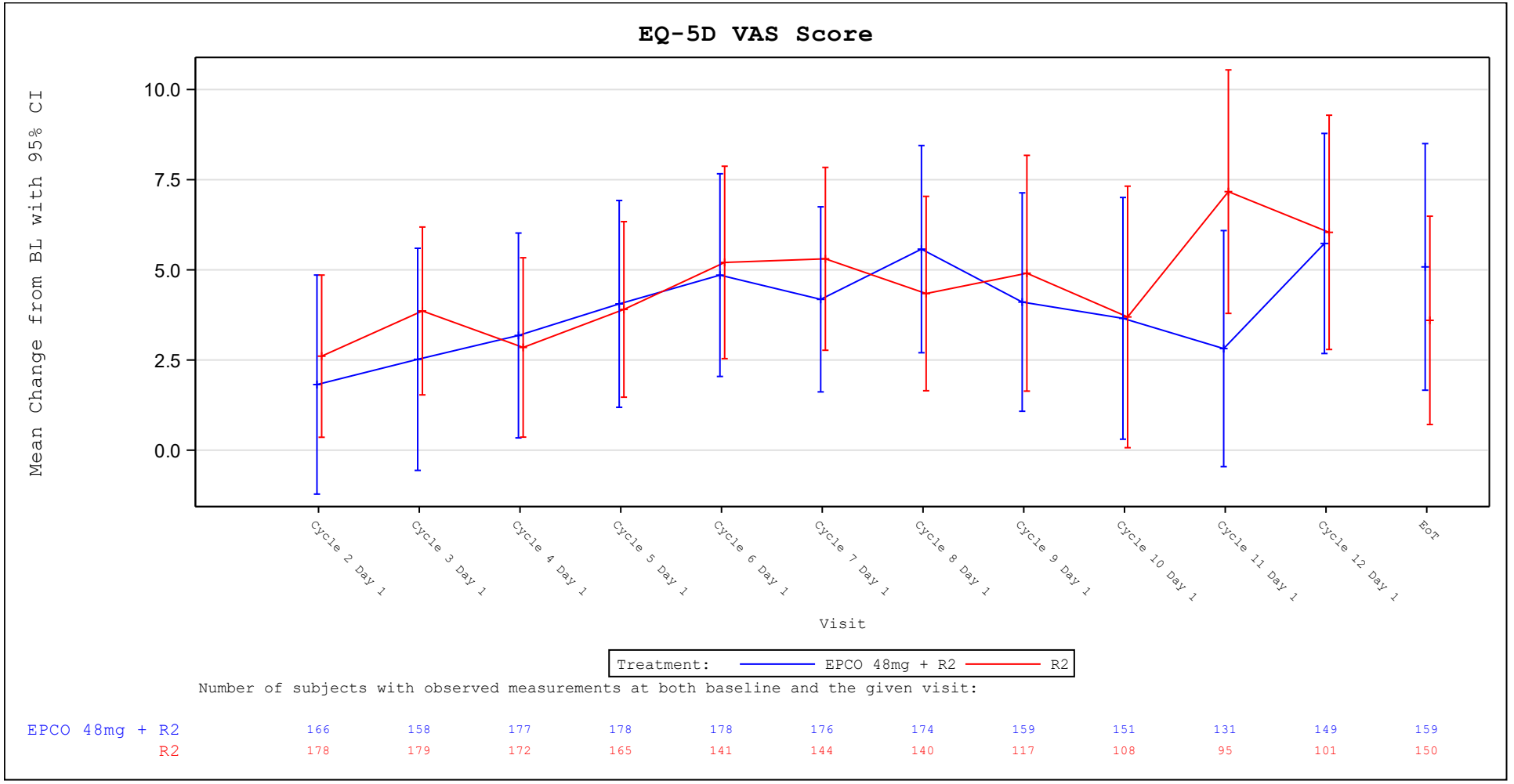
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.1.2 Summary statistics and change from baseline of EQ-5D VAS Score

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	217	73.63 (19.29)	0	-	205	73.63 (15.89)	0	-
Cycle 2 Day 1	183	74.46 (18.79)	166	1.82 (19.82)	198	75.98 (15.59)	178	2.61 (15.20)
Cycle 3 Day 1	174	75.56 (17.06)	158	2.52 (19.60)	200	77.73 (15.23)	179	3.86 (15.78)
Cycle 4 Day 1	194	77.43 (16.58)	177	3.18 (19.14)	194	76.73 (15.24)	172	2.85 (16.52)
Cycle 5 Day 1	195	78.62 (15.42)	178	4.06 (19.39)	184	77.84 (14.78)	165	3.90 (15.83)
Cycle 6 Day 1	194	78.78 (16.82)	178	4.85 (19.00)	162	78.75 (14.84)	141	5.21 (16.02)
Cycle 7 Day 1	196	79.19 (14.91)	176	4.18 (17.25)	165	79.07 (14.39)	144	5.31 (15.39)
Cycle 8 Day 1	193	79.98 (14.15)	174	5.57 (19.20)	156	78.00 (14.15)	140	4.34 (16.13)
Cycle 9 Day 1	178	78.38 (15.99)	159	4.11 (19.33)	128	78.94 (15.54)	117	4.91 (17.85)
Cycle 10 Day 1	170	77.71 (17.33)	151	3.66 (20.84)	119	78.51 (16.91)	108	3.69 (19.01)
Cycle 11 Day 1	152	77.66 (16.88)	131	2.82 (18.93)	103	79.87 (14.74)	95	7.17 (16.57)
Cycle 12 Day 1	167	78.65 (15.88)	149	5.73 (18.85)	107	80.08 (13.63)	101	6.04 (16.45)
End of Treatment	179	77.55 (17.51)	159	5.08 (21.83)	174	76.80 (15.60)	150	3.60 (17.90)
Follow up 1	92	78.62 (15.70)	83	6.43 (20.95)	66	78.83 (13.42)	58	6.55 (17.35)
Follow up 2	32	81.50 (16.68)	28	5.39 (22.55)	15	78.60 (13.29)	12	16.08 (20.19)
Follow up 3	34	76.62 (16.49)	30	9.23 (22.23)	21	79.29 (13.17)	18	2.44 (22.22)
Follow up 4	19	83.00 (13.77)	17	11.82 (19.25)	11	73.64 (14.02)	11	-9.64 (13.95)
Follow up 5	5	82.20 (19.43)	4	7.50 (32.36)	2	81.00 (1.41)	0	-
Follow up 6	3	95.00 (3.46)	2	14.50 (10.61)	1	61.00 (-)	1	-39.00 (-)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.1.3 Graphical summary of change from baseline of EQ-5D VAS Score



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	166	158	177	178	178	176	174	159	151	131	149	159
R2	178	179	172	165	141	144	140	117	108	95	101	150

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.1.4 MMRM Analysis of change from baseline of EQ-5D VAS Score

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		0.41 (1.20)		1.18 (1.18)	-0.77 (-3.75, 2.20)	0.6093	-0.05 (-0.24, 0.15)
Cycle 3 Day 1		1.19 (1.18)		2.69 (1.15)	-1.50 (-4.40, 1.40)	0.3110	-0.09 (-0.28, 0.10)
Cycle 4 Day 1		2.08 (1.14)		1.93 (1.16)	0.14 (-2.71, 3.00)	0.9208	0.01 (-0.18, 0.20)
Cycle 5 Day 1		2.89 (1.10)		3.33 (1.13)	-0.44 (-3.20, 2.31)	0.7526	-0.03 (-0.22, 0.17)
Cycle 6 Day 1		3.72 (1.14)		3.64 (1.21)	0.08 (-2.87, 3.02)	0.9582	0.00 (-0.19, 0.20)
Cycle 7 Day 1		3.80 (1.08)		3.72 (1.14)	0.08 (-2.65, 2.81)	0.9523	0.01 (-0.19, 0.20)
Cycle 8 Day 1		4.58 (1.09)		2.77 (1.15)	1.82 (-0.94, 4.58)	0.1964	0.11 (-0.08, 0.31)
Cycle 9 Day 1		2.58 (1.20)		2.44 (1.30)	0.14 (-3.04, 3.31)	0.9331	0.01 (-0.19, 0.20)
Cycle 10 Day 1		2.85 (1.32)		1.49 (1.44)	1.36 (-2.20, 4.92)	0.4531	0.07 (-0.12, 0.26)
Cycle 11 Day 1		3.28 (1.22)		3.31 (1.32)	-0.03 (-3.28, 3.22)	0.9847	-0.00 (-0.20, 0.19)
Cycle 12 Day 1		4.30 (1.16)		3.76 (1.26)	0.53 (-2.52, 3.59)	0.7312	0.03 (-0.16, 0.22)
End of Treatment		4.16 (1.27)		3.06 (1.30)	1.10 (-2.19, 4.38)	0.5113	0.06 (-0.13, 0.25)
OVERALL	214	1.89 (0.95)	198	1.94 (0.96)	-0.05 (-2.28, 2.17)	0.9615	-0.00 (-0.20, 0.19)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.1.4.S MMRM Analysis of change from baseline of EQ-5D VAS Score - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	EPCO 48mg + R2 (N=243) Baseline Mean (SD)	EPCO 48mg + R2 (N=243) Change from BL n*	EPCO 48mg + R2 (N=243) Change from BL LSMean (SE)	R2 (N=245) Baseline n	R2 (N=245) Baseline Mean (SD)	R2 (N=245) Change from BL n*	R2 (N=245) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.0239
<65	140	74.15 (18.89)	138	7.26 (1.40)	121	75.29 (14.87)	115	3.43 (1.52)	3.83 (-0.24, 7.90)	0.0648	0.23 (-0.01, 0.48)	
>=65	77	72.69 (20.08)	76	1.60 (1.95)	84	71.25 (17.07)	83	5.46 (1.88)	-3.86 (-9.22, 1.50)	0.1562	-0.23 (-0.54, 0.09)	
Sex												0.1284
Male	121	74.09 (18.71)	119	6.55 (1.46)	119	74.45 (15.13)	114	3.12 (1.51)	3.43 (-0.72, 7.58)	0.1047	0.21 (-0.04, 0.47)	
Female	96	73.05 (20.07)	95	3.26 (1.85)	86	72.51 (16.92)	84	5.01 (1.94)	-1.75 (-7.05, 3.54)	0.5143	-0.10 (-0.39, 0.20)	
Disease Status 2L												0.4654
2L: progression of disease <= 2 years	54	76.52 (19.24)	53	6.18 (2.25)	51	73.94 (17.70)	47	3.86 (2.43)	2.32 (-4.27, 8.91)	0.4859	0.14 (-0.25, 0.53)	
2L: progression of disease > 2 years	86	72.30 (21.44)	85	3.65 (2.02)	84	75.18 (14.55)	82	4.53 (2.04)	-0.88 (-6.56, 4.80)	0.7593	-0.05 (-0.35, 0.26)	
Disease Status 3L+												NE
3L+: < 6 months	19	77.42 (15.40)	18	NE	18	68.56 (17.30)	17	NE	NE		NE	
3L+: >= 6 months	58	71.67 (16.91)	58	5.30 (1.96)	52	72.60 (15.65)	52	3.62 (2.05)	1.68 (-3.96, 7.32)	0.5560	0.11 (-0.26, 0.49)	
Region												0.8361
US/Western Europe	50	72.48 (18.78)	50	4.47 (2.61)	51	71.59 (15.87)	50	2.68 (2.60)	1.79 (-5.54, 9.12)	0.6287	0.10 (-0.30, 0.49)	
Rest of world	167	73.98 (19.48)	164	5.33 (1.28)	154	74.31 (15.89)	148	4.40 (1.35)	0.93 (-2.74, 4.61)	0.6166	0.06 (-0.17, 0.28)	
Number of prior anti-lymphoma therapies												0.4585
2L	140	73.93 (20.65)	138	4.37 (1.53)	135	74.71 (15.76)	129	3.98 (1.59)	0.39 (-3.96, 4.73)	0.8616	0.02 (-0.22, 0.26)	
3L+	77	73.09 (16.64)	76	6.62 (1.73)	70	71.56 (16.06)	69	3.77 (1.81)	2.86 (-2.09, 7.80)	0.2551	0.19 (-0.14, 0.52)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.2.1 Completion rates of FACT-Lymphoma Total Score

	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	221/ 243	90.9%	214/ 245	87.3%
Cycle 2 Day 1	189/ 243	77.8%	204/ 244	83.6%
Cycle 3 Day 1	179/ 241	74.3%	205/ 236	86.9%
Cycle 4 Day 1	198/ 240	82.5%	203/ 234	86.8%
Cycle 5 Day 1	197/ 240	82.1%	188/ 233	80.7%
Cycle 6 Day 1	195/ 239	81.6%	167/ 233	71.7%
Cycle 7 Day 1	197/ 236	83.5%	167/ 229	72.9%
Cycle 8 Day 1	197/ 234	84.2%	157/ 226	69.5%
Cycle 9 Day 1	179/ 227	78.9%	129/ 220	58.6%
Cycle 10 Day 1	171/ 221	77.4%	120/ 214	56.1%
Cycle 11 Day 1	154/ 209	73.7%	105/ 199	52.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	181/ 243	74.5%	177/ 245	72.2%
Follow up 1	96		90	
Follow up 2	38		37	
Follow up 3	39		40	
Follow up 4	21		20	
Follow up 5	6		6	
Follow up 6	4		2	

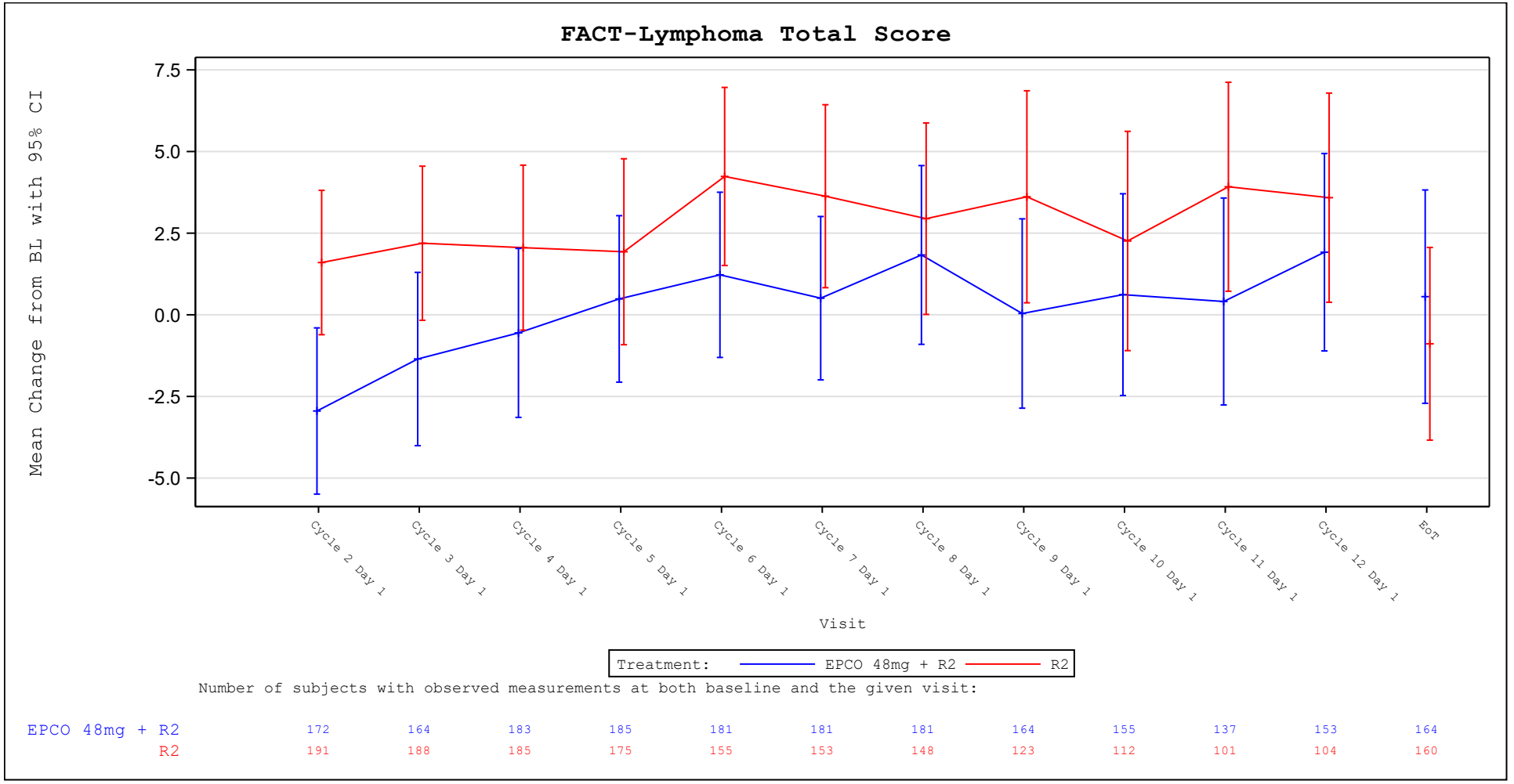
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.2.2 Summary statistics and change from baseline of FACT-Lymphoma Total Score

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	221	128.24 (19.97)	0	-	214	125.17 (21.52)	0	-
Cycle 2 Day 1	189	125.51 (22.84)	172	-2.95 (16.91)	204	127.30 (20.78)	191	1.60 (15.49)
Cycle 3 Day 1	179	126.49 (21.25)	164	-1.35 (17.21)	205	127.58 (20.69)	188	2.19 (16.40)
Cycle 4 Day 1	198	128.38 (21.25)	183	-0.55 (17.74)	203	128.12 (20.08)	185	2.06 (17.42)
Cycle 5 Day 1	197	129.19 (21.46)	185	0.49 (17.57)	188	127.89 (22.12)	175	1.93 (19.08)
Cycle 6 Day 1	195	130.16 (20.87)	181	1.22 (17.25)	167	129.90 (20.63)	155	4.24 (17.18)
Cycle 7 Day 1	197	130.16 (21.14)	181	0.51 (17.05)	167	129.86 (20.81)	153	3.63 (17.54)
Cycle 8 Day 1	197	130.33 (21.93)	181	1.83 (18.66)	157	129.25 (21.22)	148	2.94 (18.05)
Cycle 9 Day 1	179	129.50 (21.24)	164	0.04 (18.80)	129	131.60 (21.47)	123	3.61 (18.19)
Cycle 10 Day 1	171	128.60 (22.35)	155	0.62 (19.47)	120	130.08 (21.26)	112	2.26 (17.93)
Cycle 11 Day 1	154	128.55 (22.11)	137	0.41 (18.76)	105	131.53 (20.32)	101	3.92 (16.21)
Cycle 12 Day 1	167	129.07 (21.93)	153	1.92 (18.92)	107	131.02 (20.39)	104	3.59 (16.47)
End of Treatment	181	127.76 (23.28)	164	0.56 (21.19)	177	124.40 (22.70)	160	-0.89 (18.90)
Follow up 1	96	130.38 (23.31)	89	1.82 (21.58)	90	130.60 (19.21)	81	6.58 (20.69)
Follow up 2	38	136.89 (20.78)	35	8.34 (16.56)	37	130.73 (20.56)	32	9.15 (26.98)
Follow up 3	39	131.03 (23.90)	36	5.71 (22.53)	40	129.80 (21.06)	36	4.34 (25.06)
Follow up 4	21	144.06 (18.28)	19	13.13 (16.96)	20	130.64 (26.43)	20	5.65 (24.77)
Follow up 5	6	144.06 (11.21)	5	12.70 (18.41)	6	145.86 (12.77)	4	19.13 (45.68)
Follow up 6	4	154.17 (11.08)	3	4.44 (6.99)	2	99.17 (5.42)	2	-19.17 (0.71)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.2.3 Graphical summary of change from baseline of FACT-Lymphoma Total Score



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	172	164	183	185	181	181	181	164	155	137	153	164
R2	191	188	185	175	155	153	148	123	112	101	104	160

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.2.4 MMRM Analysis of change from baseline of FACT-Lymphoma Total Score

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		-2.84 (1.27)		0.24 (1.24)	-3.07 (-6.11, -0.04)	0.0472	-0.17 (-0.36, 0.02)
Cycle 3 Day 1		-1.90 (1.27)		0.94 (1.26)	-2.84 (-5.91, 0.22)	0.0686	-0.15 (-0.34, 0.04)
Cycle 4 Day 1		-0.78 (1.28)		1.54 (1.30)	-2.32 (-5.48, 0.83)	0.1489	-0.12 (-0.31, 0.07)
Cycle 5 Day 1		0.23 (1.34)		0.83 (1.37)	-0.60 (-3.96, 2.75)	0.7239	-0.03 (-0.22, 0.16)
Cycle 6 Day 1		0.90 (1.29)		2.55 (1.34)	-1.65 (-4.88, 1.58)	0.3152	-0.09 (-0.28, 0.10)
Cycle 7 Day 1		0.62 (1.31)		1.29 (1.37)	-0.67 (-3.98, 2.63)	0.6893	-0.03 (-0.22, 0.16)
Cycle 8 Day 1		1.36 (1.36)		0.71 (1.43)	0.64 (-2.85, 4.14)	0.7171	0.03 (-0.16, 0.22)
Cycle 9 Day 1		-0.21 (1.41)		1.54 (1.50)	-1.75 (-5.41, 1.92)	0.3490	-0.08 (-0.27, 0.11)
Cycle 10 Day 1		-0.56 (1.47)		-0.24 (1.58)	-0.32 (-4.19, 3.55)	0.8708	-0.01 (-0.20, 0.18)
Cycle 11 Day 1		0.10 (1.43)		2.50 (1.54)	-2.39 (-6.15, 1.36)	0.2113	-0.11 (-0.30, 0.08)
Cycle 12 Day 1		-0.11 (1.44)		0.33 (1.54)	-0.44 (-4.21, 3.33)	0.8191	-0.02 (-0.21, 0.17)
End of Treatment		0.07 (1.48)		-0.82 (1.52)	0.89 (-2.93, 4.71)	0.6453	0.04 (-0.15, 0.23)
OVERALL	219	-1.19 (1.11)	207	0.52 (1.13)	-1.71 (-4.31, 0.90)	0.1984	-0.10 (-0.29, 0.09)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.2.4.S MMRM Analysis of change from baseline of FACT-Lymphoma Total Score - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	EPCO 48mg + R2 (N=243) Baseline Mean (SD)	EPCO 48mg + R2 (N=243) Change from BL n*	EPCO 48mg + R2 (N=243) Change from BL LSMean (SE)	R2 (N=245) Baseline n	R2 (N=245) Baseline Mean (SD)	R2 (N=245) Change from BL n*	R2 (N=245) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.2583
<65	143	127.72 (20.23)	142	3.10 (1.71)	127	125.90 (21.84)	121	0.58 (1.85)	2.51 (-2.45, 7.48)	0.3199	0.12 (-0.12, 0.37)	
>=65	78	129.19 (19.58)	77	-3.96 (2.11)	87	124.11 (21.12)	86	-2.11 (2.02)	-1.85 (-7.62, 3.92)	0.5277	-0.10 (-0.41, 0.21)	
Sex												0.2936
Male	123	128.72 (19.88)	122	1.01 (1.76)	123	126.03 (21.57)	118	-1.72 (1.81)	2.74 (-2.24, 7.71)	0.2797	0.14 (-0.11, 0.39)	
Female	98	127.64 (20.17)	97	-0.04 (2.06)	91	124.01 (21.52)	89	1.31 (2.13)	-1.35 (-7.20, 4.49)	0.6487	-0.07 (-0.35, 0.22)	
Disease Status 2L												0.2310
2L: progression of disease <= 2 years	56	126.82 (21.64)	55	3.41 (2.19)	53	120.33 (25.22)	49	-1.40 (2.36)	4.81 (-1.59, 11.21)	0.1390	0.29 (-0.10, 0.68)	
2L: progression of disease > 2 years	87	130.52 (20.67)	86	-1.80 (2.23)	89	130.18 (19.67)	87	-1.21 (2.22)	-0.58 (-6.80, 5.63)	0.8527	-0.03 (-0.33, 0.27)	
Disease Status 3L+												NE
3L+: < 6 months	19	129.97 (17.78)	19	NE	18	121.77 (20.28)	17	NE	NE		NE	
3L+: >= 6 months	59	125.67 (17.89)	59	-1.76 (2.84)	54	122.80 (19.67)	54	2.48 (2.93)	-4.24 (-12.34, 3.87)	0.3019	-0.19 (-0.56, 0.18)	
Region												0.9505
US/Western Europe	50	124.54 (23.21)	50	0.15 (2.93)	53	126.16 (18.50)	52	-1.18 (2.89)	1.33 (-6.83, 9.49)	0.7472	0.06 (-0.32, 0.45)	
Rest of world	171	129.32 (18.86)	169	0.57 (1.52)	161	124.85 (22.47)	155	-0.47 (1.59)	1.04 (-3.29, 5.37)	0.6371	0.05 (-0.17, 0.27)	
Number of prior anti-lymphoma therapies												0.7855
2L	143	129.07 (21.06)	141	0.09 (1.63)	142	126.50 (22.34)	136	-1.35 (1.67)	1.43 (-3.16, 6.03)	0.5396	0.07 (-0.16, 0.31)	
3L+	78	126.72 (17.84)	78	1.25 (2.44)	72	122.54 (19.69)	71	0.97 (2.55)	0.28 (-6.70, 7.27)	0.9362	0.01 (-0.31, 0.33)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.3.1 Completion rates of FACT-G Total Score

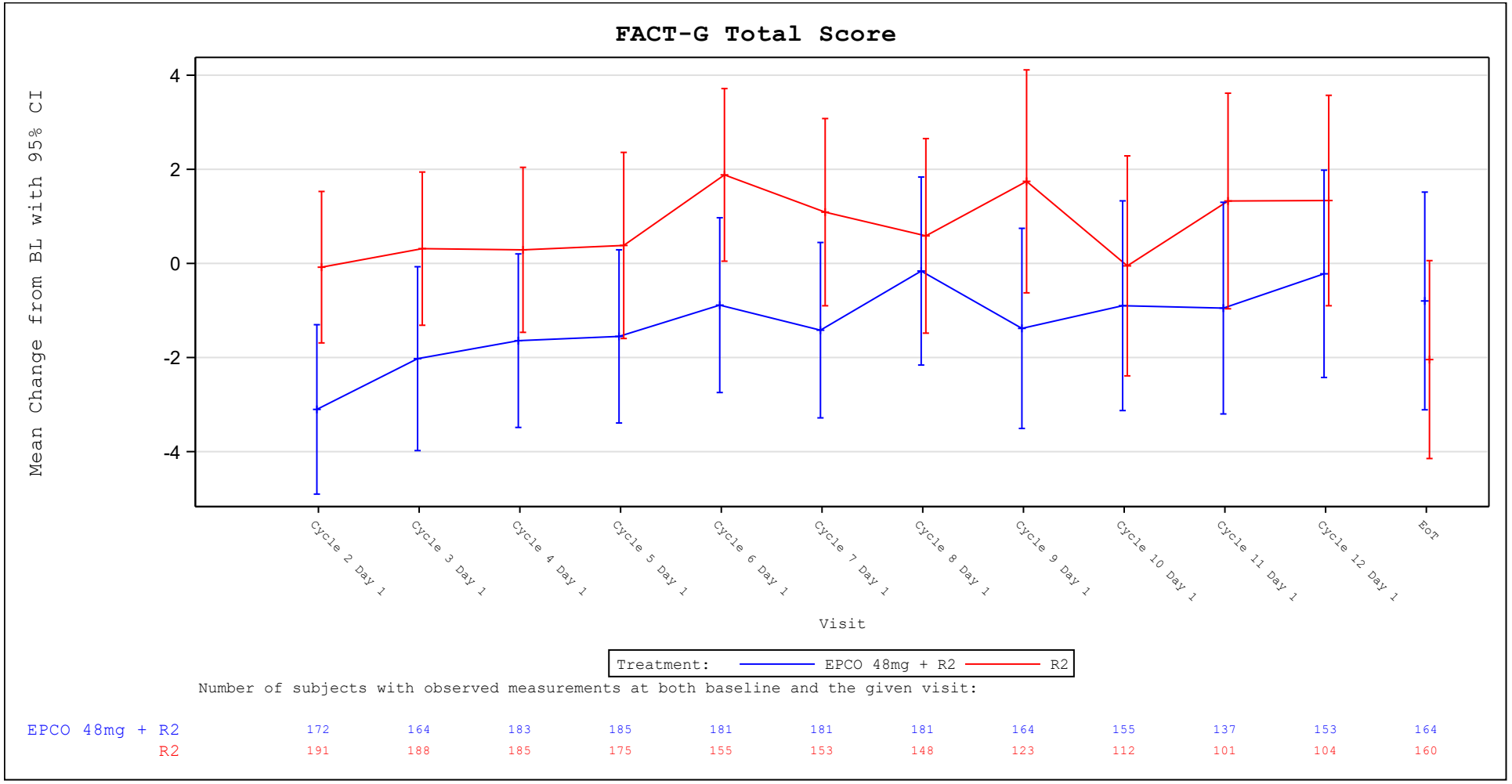
	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	221/ 243	90.9%	214/ 245	87.3%
Cycle 2 Day 1	189/ 243	77.8%	204/ 244	83.6%
Cycle 3 Day 1	179/ 241	74.3%	205/ 236	86.9%
Cycle 4 Day 1	198/ 240	82.5%	203/ 234	86.8%
Cycle 5 Day 1	197/ 240	82.1%	188/ 233	80.7%
Cycle 6 Day 1	195/ 239	81.6%	167/ 233	71.7%
Cycle 7 Day 1	197/ 236	83.5%	167/ 229	72.9%
Cycle 8 Day 1	197/ 234	84.2%	157/ 226	69.5%
Cycle 9 Day 1	179/ 227	78.9%	129/ 220	58.6%
Cycle 10 Day 1	171/ 221	77.4%	120/ 214	56.1%
Cycle 11 Day 1	154/ 209	73.7%	105/ 199	52.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	181/ 243	74.5%	177/ 245	72.2%
Follow up 1	96		90	
Follow up 2	38		37	
Follow up 3	39		40	
Follow up 4	21		20	
Follow up 5	6		6	
Follow up 6	4		2	

n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.3.2 Summary statistics and change from baseline of FACT-G Total Score

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	221	81.43 (13.84)	0	-	214	79.07 (14.74)	0	-
Cycle 2 Day 1	189	78.40 (15.76)	172	-3.10 (11.96)	204	79.56 (14.17)	191	-0.08 (11.28)
Cycle 3 Day 1	179	79.02 (14.81)	164	-2.02 (12.67)	205	79.77 (13.87)	188	0.31 (11.32)
Cycle 4 Day 1	198	80.24 (14.94)	183	-1.64 (12.64)	203	80.09 (13.61)	185	0.29 (12.09)
Cycle 5 Day 1	197	80.13 (15.27)	185	-1.55 (12.69)	188	80.04 (15.31)	175	0.38 (13.25)
Cycle 6 Day 1	195	80.88 (15.32)	181	-0.89 (12.66)	167	81.48 (13.77)	155	1.88 (11.56)
Cycle 7 Day 1	197	80.87 (15.50)	181	-1.42 (12.71)	167	80.99 (14.46)	153	1.09 (12.45)
Cycle 8 Day 1	197	81.15 (15.56)	181	-0.16 (13.62)	157	80.54 (14.88)	148	0.59 (12.73)
Cycle 9 Day 1	179	80.75 (15.60)	164	-1.38 (13.79)	129	82.78 (14.82)	123	1.74 (13.27)
Cycle 10 Day 1	171	80.25 (15.88)	155	-0.90 (14.04)	120	81.12 (15.20)	112	-0.05 (12.49)
Cycle 11 Day 1	154	80.01 (16.17)	137	-0.95 (13.31)	105	82.23 (14.82)	101	1.33 (11.61)
Cycle 12 Day 1	167	80.30 (15.78)	153	-0.22 (13.79)	107	81.96 (14.49)	104	1.34 (11.50)
End of Treatment	181	79.77 (16.03)	164	-0.80 (15.00)	177	77.14 (16.01)	160	-2.04 (13.47)
Follow up 1	96	81.51 (16.72)	89	-0.39 (15.63)	90	80.72 (13.33)	81	2.77 (15.45)
Follow up 2	38	85.73 (14.42)	35	3.62 (11.95)	37	80.75 (15.26)	32	2.96 (19.93)
Follow up 3	39	81.51 (17.22)	36	1.88 (15.10)	40	80.85 (14.49)	36	0.68 (18.38)
Follow up 4	21	90.87 (12.51)	19	7.50 (11.80)	20	81.74 (16.97)	20	4.00 (18.04)
Follow up 5	6	88.56 (9.72)	5	7.10 (11.77)	6	91.36 (9.59)	4	12.38 (30.92)
Follow up 6	4	96.67 (10.59)	3	3.44 (8.58)	2	63.67 (8.96)	2	-9.67 (5.66)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	172	164	183	185	181	181	181	164	155	137	153	164
R2	191	188	185	175	155	153	148	123	112	101	104	160

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.3.4 MMRM Analysis of change from baseline of FACT-G Total Score

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		-2.92 (0.90)		-0.91 (0.89)	-2.01 (-4.18, 0.16)	0.0694	-0.15 (-0.34, 0.04)
Cycle 3 Day 1		-2.49 (0.90)		-0.57 (0.89)	-1.93 (-4.09, 0.23)	0.0804	-0.15 (-0.34, 0.04)
Cycle 4 Day 1		-1.76 (0.91)		-0.19 (0.92)	-1.56 (-3.78, 0.65)	0.1660	-0.12 (-0.31, 0.07)
Cycle 5 Day 1		-1.63 (0.95)		-0.50 (0.98)	-1.13 (-3.51, 1.26)	0.3545	-0.08 (-0.27, 0.11)
Cycle 6 Day 1		-1.08 (0.92)		0.61 (0.96)	-1.69 (-3.99, 0.60)	0.1482	-0.12 (-0.31, 0.07)
Cycle 7 Day 1		-1.42 (0.95)		-0.53 (1.00)	-0.88 (-3.30, 1.53)	0.4719	-0.06 (-0.25, 0.13)
Cycle 8 Day 1		-0.67 (0.99)		-0.99 (1.04)	0.32 (-2.21, 2.85)	0.8043	0.02 (-0.17, 0.21)
Cycle 9 Day 1		-1.77 (1.02)		-0.12 (1.08)	-1.65 (-4.30, 1.01)	0.2235	-0.11 (-0.30, 0.08)
Cycle 10 Day 1		-2.01 (1.05)		-1.60 (1.13)	-0.41 (-3.19, 2.36)	0.7703	-0.03 (-0.22, 0.16)
Cycle 11 Day 1		-1.53 (1.04)		0.43 (1.11)	-1.96 (-4.68, 0.77)	0.1581	-0.12 (-0.32, 0.07)
Cycle 12 Day 1		-1.65 (1.03)		-1.02 (1.11)	-0.63 (-3.35, 2.09)	0.6484	-0.04 (-0.23, 0.15)
End of Treatment		-1.32 (1.06)		-2.27 (1.08)	0.95 (-1.77, 3.67)	0.4936	0.06 (-0.13, 0.25)
OVERALL	219	-2.20 (0.80)	207	-0.95 (0.81)	-1.24 (-3.12, 0.63)	0.1933	-0.11 (-0.30, 0.08)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.3.4.S MMRM Analysis of change from baseline of FACT-G Total Score - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	EPCO 48mg + R2 (N=243) Baseline Mean (SD)	EPCO 48mg + R2 (N=243) Change from BL n*	EPCO 48mg + R2 (N=243) Change from BL LSMean (SE)	R2 (N=245) Baseline n	R2 (N=245) Baseline Mean (SD)	R2 (N=245) Change from BL n*	R2 (N=245) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.1681
<65	143	81.27 (13.92)	142	0.84 (1.19)	127	79.77 (15.04)	121	-1.59 (1.29)	2.43 (-1.02, 5.88)	0.1671	0.17 (-0.07, 0.41)	
>=65	78	81.72 (13.76)	77	-4.16 (1.58)	87	78.06 (14.32)	86	-2.72 (1.51)	-1.44 (-5.76, 2.89)	0.5126	-0.10 (-0.41, 0.21)	
Sex												0.1650
Male	123	81.40 (13.79)	122	-0.28 (1.24)	123	79.37 (14.79)	118	-2.94 (1.27)	2.65 (-0.85, 6.16)	0.1368	0.19 (-0.06, 0.45)	
Female	98	81.47 (13.97)	97	-1.84 (1.47)	91	78.67 (14.74)	89	-0.66 (1.52)	-1.18 (-5.36, 2.99)	0.5773	-0.08 (-0.37, 0.21)	
Disease Status 2L												0.1867
2L: progression of disease <= 2 years	56	80.41 (15.21)	55	1.17 (1.58)	53	75.84 (17.09)	49	-2.99 (1.70)	4.16 (-0.45, 8.78)	0.0764	0.35 (-0.04, 0.74)	
2L: progression of disease > 2 years	87	82.75 (14.15)	86	-2.71 (1.57)	89	82.58 (13.22)	87	-2.63 (1.56)	-0.08 (-4.45, 4.30)	0.9722	-0.01 (-0.30, 0.29)	
Disease Status 3L+												NE
3L+: < 6 months	19	83.76 (12.13)	19	NE	18	76.88 (14.79)	17	NE	NE		NE	
3L+: >= 6 months	59	79.70 (12.48)	59	-2.45 (2.06)	54	77.21 (13.79)	54	0.22 (2.13)	-2.68 (-8.55, 3.20)	0.3681	-0.17 (-0.54, 0.20)	
Region												0.7405
US/Western Europe	50	79.24 (15.43)	50	-1.25 (1.97)	53	80.35 (12.28)	52	-3.21 (1.95)	1.96 (-3.55, 7.47)	0.4820	0.14 (-0.25, 0.53)	
Rest of world	171	82.07 (13.31)	169	-1.02 (1.10)	161	78.65 (15.47)	155	-1.92 (1.15)	0.90 (-2.23, 4.03)	0.5719	0.06 (-0.16, 0.28)	
Number of prior anti-lymphoma therapies												0.7559
2L	143	81.83 (14.57)	141	-1.26 (1.16)	142	80.06 (15.08)	136	-2.76 (1.18)	1.50 (-1.75, 4.76)	0.3641	0.11 (-0.13, 0.34)	
3L+	78	80.69 (12.44)	78	-0.57 (1.77)	72	77.13 (13.94)	71	-1.12 (1.85)	0.55 (-4.52, 5.63)	0.8292	0.04 (-0.29, 0.36)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.4.1 Completion rates of Subscale Physical Well-Being

	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	221/ 243	90.9%	214/ 245	87.3%
Cycle 2 Day 1	189/ 243	77.8%	204/ 244	83.6%
Cycle 3 Day 1	179/ 241	74.3%	205/ 236	86.9%
Cycle 4 Day 1	198/ 240	82.5%	203/ 234	86.8%
Cycle 5 Day 1	197/ 240	82.1%	188/ 233	80.7%
Cycle 6 Day 1	195/ 239	81.6%	167/ 233	71.7%
Cycle 7 Day 1	197/ 236	83.5%	167/ 229	72.9%
Cycle 8 Day 1	197/ 234	84.2%	157/ 226	69.5%
Cycle 9 Day 1	179/ 227	78.9%	129/ 220	58.6%
Cycle 10 Day 1	171/ 221	77.4%	120/ 214	56.1%
Cycle 11 Day 1	154/ 209	73.7%	105/ 199	52.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	181/ 243	74.5%	177/ 245	72.2%
Follow up 1	96		90	
Follow up 2	38		37	
Follow up 3	39		40	
Follow up 4	21		20	
Follow up 5	6		6	
Follow up 6	4		2	

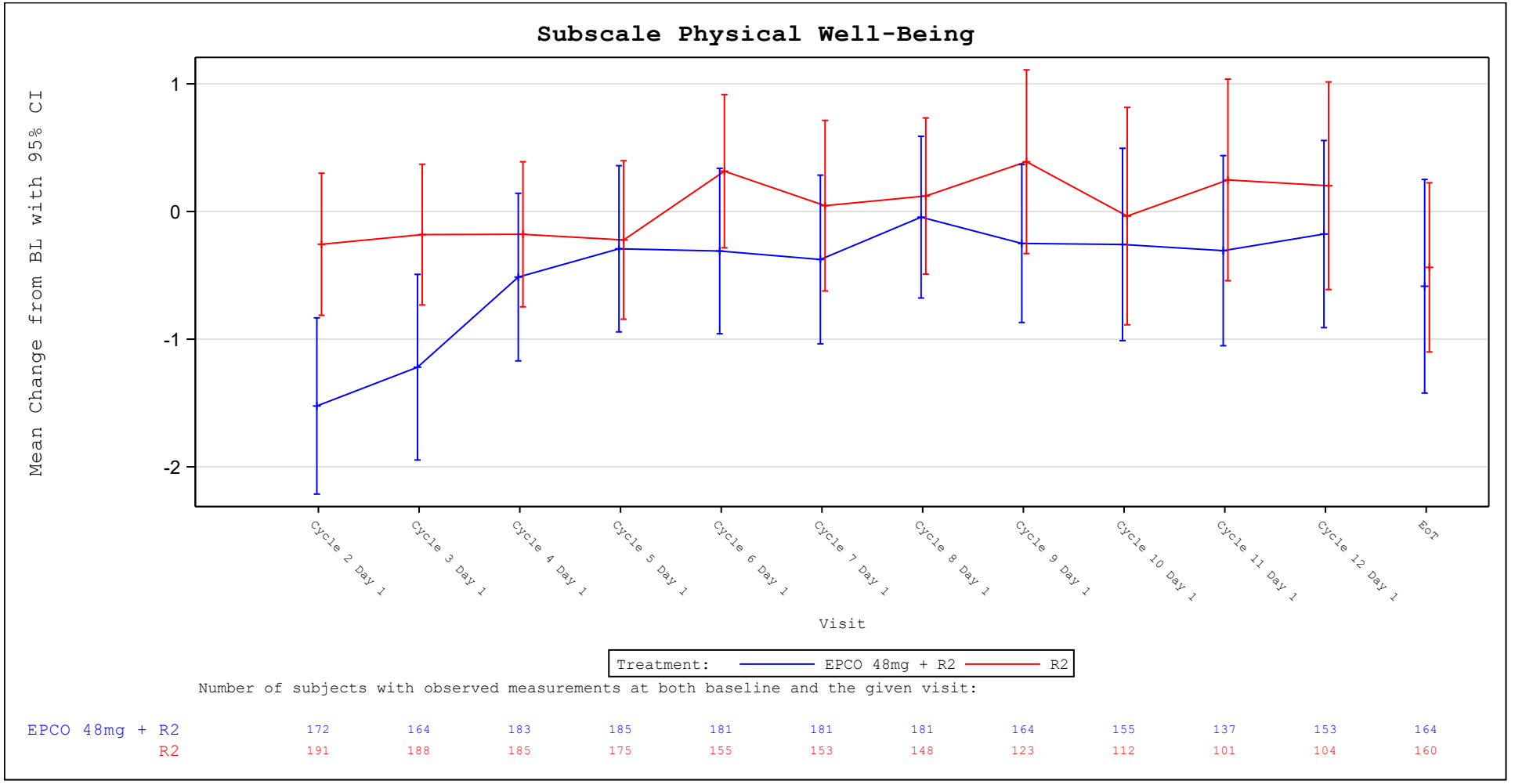
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.4.2 Summary statistics and change from baseline of Subscale Physical Well-Being

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	221	23.39 (4.09)	0	-	214	22.85 (4.40)	0	-
Cycle 2 Day 1	189	21.84 (5.16)	172	-1.52 (4.59)	204	22.66 (4.69)	191	-0.26 (3.90)
Cycle 3 Day 1	179	22.15 (4.81)	164	-1.22 (4.72)	205	22.82 (4.34)	188	-0.18 (3.83)
Cycle 4 Day 1	198	22.92 (4.31)	183	-0.51 (4.50)	203	22.88 (4.39)	185	-0.18 (3.92)
Cycle 5 Day 1	197	23.31 (4.43)	185	-0.29 (4.49)	188	22.87 (4.55)	175	-0.22 (4.16)
Cycle 6 Day 1	195	23.24 (4.51)	181	-0.31 (4.42)	167	23.28 (4.11)	155	0.32 (3.78)
Cycle 7 Day 1	197	23.27 (4.38)	181	-0.38 (4.51)	167	23.24 (4.33)	153	0.05 (4.18)
Cycle 8 Day 1	197	23.52 (4.53)	181	-0.04 (4.32)	157	23.29 (4.32)	148	0.12 (3.77)
Cycle 9 Day 1	179	23.35 (4.09)	164	-0.25 (4.02)	129	23.80 (4.18)	123	0.39 (4.03)
Cycle 10 Day 1	171	23.12 (4.60)	155	-0.26 (4.75)	120	23.20 (4.39)	112	-0.04 (4.55)
Cycle 11 Day 1	154	23.31 (4.73)	137	-0.31 (4.41)	105	23.32 (4.26)	101	0.25 (4.00)
Cycle 12 Day 1	167	23.12 (4.34)	153	-0.18 (4.59)	107	23.29 (4.37)	104	0.20 (4.18)
End of Treatment	181	22.66 (5.13)	164	-0.59 (5.43)	177	22.44 (4.96)	160	-0.44 (4.24)
Follow up 1	96	23.53 (4.79)	89	-0.02 (5.00)	90	24.31 (3.78)	81	1.38 (4.25)
Follow up 2	38	24.92 (3.68)	35	1.60 (4.57)	37	24.05 (4.40)	32	1.75 (6.87)
Follow up 3	39	24.05 (4.12)	36	0.78 (4.70)	40	23.90 (4.76)	36	0.67 (5.79)
Follow up 4	21	26.10 (2.62)	19	1.74 (3.98)	20	23.93 (5.51)	20	0.68 (6.67)
Follow up 5	6	25.00 (4.00)	5	0.60 (6.19)	6	26.50 (1.38)	4	2.00 (4.69)
Follow up 6	4	27.25 (1.50)	3	-0.33 (1.53)	2	14.50 (0.71)	2	-7.50 (4.95)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.4.3 Graphical summary of change from baseline of Subscale Physical Well-Being



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	172	164	183	185	181	181	181	164	155	137	153	164
R2	191	188	185	175	155	153	148	123	112	101	104	160

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.4.4 MMRM Analysis of change from baseline of Subscale Physical Well-Being

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		-1.65 (0.32)		-0.71 (0.32)	-0.95 (-1.74, -0.15)	0.0203	-0.20 (-0.39, -0.01)
Cycle 3 Day 1		-1.50 (0.31)		-0.46 (0.31)	-1.04 (-1.81, -0.27)	0.0080	-0.23 (-0.42, -0.04)
Cycle 4 Day 1		-0.79 (0.30)		-0.44 (0.30)	-0.35 (-1.09, 0.39)	0.3496	-0.08 (-0.27, 0.11)
Cycle 5 Day 1		-0.40 (0.31)		-0.45 (0.32)	0.05 (-0.74, 0.85)	0.8922	0.01 (-0.18, 0.20)
Cycle 6 Day 1		-0.54 (0.30)		-0.11 (0.31)	-0.43 (-1.19, 0.32)	0.2615	-0.10 (-0.29, 0.09)
Cycle 7 Day 1		-0.62 (0.31)		-0.38 (0.33)	-0.24 (-1.05, 0.56)	0.5546	-0.05 (-0.24, 0.14)
Cycle 8 Day 1		-0.31 (0.30)		-0.37 (0.32)	0.06 (-0.71, 0.83)	0.8767	0.01 (-0.18, 0.20)
Cycle 9 Day 1		-0.55 (0.31)		-0.08 (0.33)	-0.47 (-1.26, 0.32)	0.2454	-0.10 (-0.29, 0.09)
Cycle 10 Day 1		-0.61 (0.35)		-0.65 (0.38)	0.04 (-0.90, 0.98)	0.9300	0.01 (-0.18, 0.20)
Cycle 11 Day 1		-0.35 (0.34)		-0.27 (0.37)	-0.08 (-0.99, 0.83)	0.8599	-0.02 (-0.21, 0.17)
Cycle 12 Day 1		-0.65 (0.33)		-0.46 (0.37)	-0.19 (-1.07, 0.70)	0.6783	-0.04 (-0.23, 0.15)
End of Treatment		-0.68 (0.35)		-0.56 (0.36)	-0.12 (-1.03, 0.79)	0.7924	-0.02 (-0.21, 0.17)
OVERALL	219	-0.90 (0.25)	207	-0.55 (0.26)	-0.35 (-0.94, 0.23)	0.2373	-0.10 (-0.29, 0.09)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.4.4.S MMRM Analysis of change from baseline of Subscale Physical Well-Being - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	EPCO 48mg + R2 (N=243) Baseline Mean (SD)	EPCO 48mg + R2 (N=243) Change from BL n*	EPCO 48mg + R2 (N=243) Change from BL LSMean (SE)	R2 (N=245) Baseline n	R2 (N=245) Baseline Mean (SD)	R2 (N=245) Change from BL n*	R2 (N=245) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.0135
<65	143	23.10 (4.23)	142	0.60 (0.36)	127	22.80 (4.27)	121	-0.21 (0.39)	0.81 (-0.23, 1.86)	0.1276	0.19 (-0.05, 0.43)	
>=65	78	23.92 (3.78)	77	-2.29 (0.61)	87	22.93 (4.60)	86	-0.64 (0.58)	-1.65 (-3.31, 0.02)	0.0523	-0.31 (-0.62, 0.00)	
Sex												0.4042
Male	123	23.76 (4.23)	122	-0.29 (0.40)	123	23.08 (4.48)	118	-0.58 (0.41)	0.29 (-0.84, 1.42)	0.6108	0.07 (-0.19, 0.32)	
Female	98	22.92 (3.87)	97	-0.66 (0.54)	91	22.54 (4.29)	89	-0.15 (0.55)	-0.51 (-2.04, 1.02)	0.5099	-0.10 (-0.38, 0.19)	
Disease Status 2L												0.0532
2L: progression of disease <= 2 years	56	22.64 (4.72)	55	0.83 (0.60)	53	21.96 (5.28)	49	-0.68 (0.64)	1.51 (-0.24, 3.25)	0.0904	0.33 (-0.05, 0.72)	
2L: progression of disease > 2 years	87	24.02 (3.86)	86	-1.13 (0.53)	89	23.56 (3.91)	87	-0.41 (0.52)	-0.72 (-2.18, 0.74)	0.3343	-0.15 (-0.45, 0.15)	
Disease Status 3L+												NE
3L+: < 6 months	19	23.00 (3.92)	19	NE	18	21.78 (4.98)	17	NE	NE		NE	
3L+: >= 6 months	59	23.29 (3.77)	59	-1.18 (0.70)	54	22.91 (3.87)	54	-0.21 (0.72)	-0.97 (-2.95, 1.02)	0.3365	-0.18 (-0.55, 0.19)	
Region												0.3744
US/Western Europe	50	23.36 (4.61)	50	-2.24 (0.71)	53	23.00 (3.74)	52	-1.38 (0.70)	-0.86 (-2.85, 1.13)	0.3936	-0.17 (-0.56, 0.22)	
Rest of world	171	23.40 (3.94)	169	0.06 (0.36)	161	22.80 (4.60)	155	-0.09 (0.37)	0.14 (-0.88, 1.17)	0.7828	0.03 (-0.19, 0.25)	
Number of prior anti-lymphoma therapies												0.8040
2L	143	23.48 (4.26)	141	-0.40 (0.40)	142	22.96 (4.52)	136	-0.50 (0.41)	0.09 (-1.04, 1.22)	0.8694	0.02 (-0.22, 0.26)	
3L+	78	23.22 (3.79)	78	-0.46 (0.57)	72	22.63 (4.17)	71	-0.30 (0.59)	-0.15 (-1.77, 1.47)	0.8513	-0.03 (-0.35, 0.29)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.5.1 Completion rates of Subscale Social/Family Well Being

	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	221/ 243	90.9%	214/ 245	87.3%
Cycle 2 Day 1	189/ 243	77.8%	204/ 244	83.6%
Cycle 3 Day 1	179/ 241	74.3%	205/ 236	86.9%
Cycle 4 Day 1	198/ 240	82.5%	203/ 234	86.8%
Cycle 5 Day 1	197/ 240	82.1%	188/ 233	80.7%
Cycle 6 Day 1	195/ 239	81.6%	167/ 233	71.7%
Cycle 7 Day 1	197/ 236	83.5%	167/ 229	72.9%
Cycle 8 Day 1	197/ 234	84.2%	157/ 226	69.5%
Cycle 9 Day 1	179/ 227	78.9%	129/ 220	58.6%
Cycle 10 Day 1	171/ 221	77.4%	120/ 214	56.1%
Cycle 11 Day 1	154/ 209	73.7%	105/ 199	52.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	181/ 243	74.5%	177/ 245	72.2%
Follow up 1	96		90	
Follow up 2	38		37	
Follow up 3	39		40	
Follow up 4	21		20	
Follow up 5	6		6	
Follow up 6	4		2	

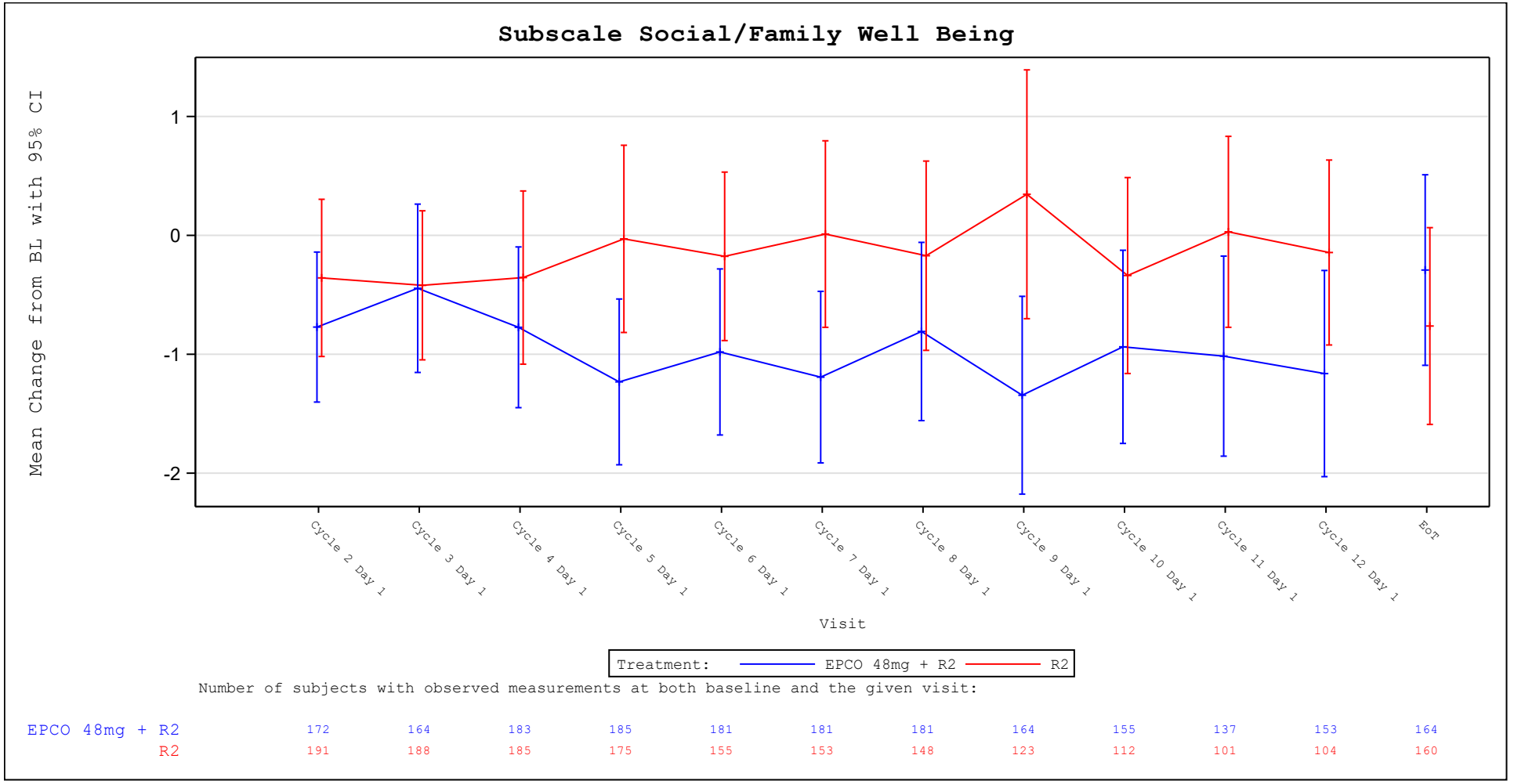
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.5.2 Summary statistics and change from baseline of Subscale Social/Family Well Being

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	221	21.35 (5.08)	0	-	214	20.57 (5.14)	0	-
Cycle 2 Day 1	189	20.64 (5.36)	172	-0.77 (4.19)	204	20.62 (5.12)	191	-0.36 (4.63)
Cycle 3 Day 1	179	20.55 (5.23)	164	-0.45 (4.59)	205	20.40 (5.02)	188	-0.42 (4.36)
Cycle 4 Day 1	198	20.56 (5.40)	183	-0.77 (4.63)	203	20.55 (4.86)	185	-0.35 (5.02)
Cycle 5 Day 1	197	20.22 (6.00)	185	-1.23 (4.81)	188	20.90 (5.24)	175	-0.03 (5.28)
Cycle 6 Day 1	195	20.40 (5.56)	181	-0.98 (4.76)	167	20.52 (4.66)	155	-0.18 (4.47)
Cycle 7 Day 1	197	20.36 (5.65)	181	-1.19 (4.92)	167	20.77 (5.03)	153	0.01 (4.91)
Cycle 8 Day 1	197	20.37 (5.59)	181	-0.81 (5.11)	157	20.59 (5.36)	148	-0.17 (4.90)
Cycle 9 Day 1	179	20.09 (5.90)	164	-1.34 (5.39)	129	21.19 (5.40)	123	0.35 (5.86)
Cycle 10 Day 1	171	20.27 (5.75)	155	-0.94 (5.12)	120	21.14 (5.04)	112	-0.34 (4.40)
Cycle 11 Day 1	154	19.99 (5.94)	137	-1.02 (4.98)	105	21.07 (5.49)	101	0.03 (4.07)
Cycle 12 Day 1	167	19.96 (6.07)	153	-1.16 (5.43)	107	21.14 (4.98)	104	-0.14 (4.00)
End of Treatment	181	20.94 (5.16)	164	-0.29 (5.20)	177	20.22 (5.23)	160	-0.76 (5.30)
Follow up 1	96	20.96 (5.57)	89	-1.07 (5.61)	90	20.49 (4.68)	81	-0.03 (5.99)
Follow up 2	38	21.47 (4.89)	35	-0.66 (5.04)	37	20.45 (6.42)	32	-0.94 (7.15)
Follow up 3	39	20.10 (5.50)	36	-0.23 (4.76)	40	21.10 (4.62)	36	0.26 (5.23)
Follow up 4	21	22.58 (3.83)	19	1.50 (4.07)	20	20.06 (5.26)	20	-0.23 (5.46)
Follow up 5	6	21.72 (6.17)	5	1.70 (8.02)	6	23.03 (3.45)	4	4.63 (11.19)
Follow up 6	4	22.92 (6.17)	3	-0.22 (2.27)	2	19.17 (4.01)	2	-0.67 (5.66)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.5.3 Graphical summary of change from baseline of Subscale Social/Family Well Being



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	172	164	183	185	181	181	181	164	155	137	153	164
R2	191	188	185	175	155	153	148	123	112	101	104	160

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.5.4 MMRM Analysis of change from baseline of Subscale Social/Family Well Being

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		-0.53 (0.34)		-0.53 (0.34)	-0.01 (-0.84, 0.83)	0.9902	-0.00 (-0.19, 0.19)
Cycle 3 Day 1		-0.69 (0.34)		-0.55 (0.33)	-0.14 (-0.95, 0.68)	0.7415	-0.03 (-0.22, 0.16)
Cycle 4 Day 1		-0.67 (0.34)		-0.44 (0.35)	-0.24 (-1.08, 0.61)	0.5790	-0.05 (-0.24, 0.14)
Cycle 5 Day 1		-1.07 (0.37)		-0.19 (0.37)	-0.88 (-1.80, 0.05)	0.0636	-0.16 (-0.35, 0.03)
Cycle 6 Day 1		-0.85 (0.33)		-0.52 (0.35)	-0.33 (-1.17, 0.50)	0.4293	-0.07 (-0.26, 0.12)
Cycle 7 Day 1		-1.01 (0.35)		-0.38 (0.37)	-0.64 (-1.54, 0.26)	0.1638	-0.12 (-0.31, 0.07)
Cycle 8 Day 1		-0.92 (0.36)		-0.54 (0.38)	-0.38 (-1.31, 0.56)	0.4302	-0.07 (-0.26, 0.12)
Cycle 9 Day 1		-1.27 (0.39)		-0.30 (0.42)	-0.97 (-2.00, 0.05)	0.0626	-0.17 (-0.36, 0.02)
Cycle 10 Day 1		-1.09 (0.38)		-0.45 (0.41)	-0.64 (-1.64, 0.36)	0.2083	-0.11 (-0.30, 0.08)
Cycle 11 Day 1		-1.11 (0.37)		-0.07 (0.40)	-1.04 (-2.02, -0.06)	0.0374	-0.18 (-0.37, 0.01)
Cycle 12 Day 1		-1.23 (0.38)		-0.53 (0.41)	-0.70 (-1.70, 0.30)	0.1682	-0.12 (-0.31, 0.07)
End of Treatment		-0.53 (0.38)		-0.99 (0.39)	0.46 (-0.51, 1.43)	0.3524	0.08 (-0.11, 0.27)
OVERALL	219	-0.65 (0.29)	207	-0.40 (0.29)	-0.25 (-0.93, 0.42)	0.4641	-0.06 (-0.25, 0.13)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.5.4.S MMRM Analysis of change from baseline of Subscale Social/Family Well Being - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	EPCO 48mg + R2 (N=243) Baseline Mean (SD)	EPCO 48mg + R2 (N=243) Change from BL n*	EPCO 48mg + R2 (N=243) Change from BL LSMean (SE)	R2 (N=245) Baseline n	R2 (N=245) Baseline Mean (SD)	R2 (N=245) Change from BL n*	R2 (N=245) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.4746
<65	143	21.46 (4.98)	142	-0.63 (0.42)	127	20.78 (5.16)	121	-0.82 (0.45)	0.19 (-1.03, 1.40)	0.7593	0.04 (-0.20, 0.28)	
>=65	78	21.14 (5.28)	77	-0.30 (0.58)	87	20.27 (5.13)	86	-1.22 (0.56)	0.92 (-0.68, 2.51)	0.2590	0.18 (-0.13, 0.49)	
Sex												0.2689
Male	123	20.85 (5.02)	122	-0.48 (0.45)	123	20.32 (5.47)	118	-1.38 (0.46)	0.90 (-0.36, 2.16)	0.1614	0.18 (-0.07, 0.43)	
Female	98	21.98 (5.12)	97	-0.56 (0.52)	91	20.92 (4.66)	89	-0.37 (0.54)	-0.19 (-1.68, 1.29)	0.7971	-0.04 (-0.33, 0.25)	
Disease Status 2L												0.4914
2L: progression of disease <= 2 years	56	21.18 (5.06)	55	-0.66 (0.65)	53	20.40 (5.59)	49	-1.75 (0.70)	1.09 (-0.82, 2.99)	0.2597	0.22 (-0.16, 0.61)	
2L: progression of disease > 2 years	87	21.66 (4.78)	86	-0.75 (0.52)	89	21.33 (4.51)	87	-1.01 (0.51)	0.26 (-1.18, 1.70)	0.7244	0.05 (-0.24, 0.35)	
Disease Status 3L+												NE
3L+: < 6 months	19	22.97 (3.84)	19	NE	18	18.99 (6.64)	17	NE	NE		NE	
3L+: >= 6 months	59	20.53 (5.79)	59	-0.06 (0.75)	54	20.02 (5.05)	54	-0.78 (0.78)	0.72 (-1.42, 2.87)	0.5056	0.12 (-0.24, 0.49)	
Region												0.7817
US/Western Europe	50	21.18 (5.14)	50	-0.12 (0.70)	53	20.69 (4.48)	52	-0.85 (0.69)	0.73 (-1.22, 2.68)	0.4591	0.15 (-0.24, 0.53)	
Rest of world	171	21.40 (5.08)	169	-0.62 (0.40)	161	20.54 (5.35)	155	-1.04 (0.41)	0.41 (-0.72, 1.55)	0.4729	0.08 (-0.14, 0.30)	
Number of prior anti-lymphoma therapies												0.8804
2L	143	21.47 (4.88)	141	-0.68 (0.40)	142	20.98 (4.94)	136	-1.17 (0.41)	0.49 (-0.64, 1.62)	0.3920	0.10 (-0.13, 0.34)	
3L+	78	21.13 (5.46)	78	-0.08 (0.64)	72	19.77 (5.46)	71	-0.74 (0.67)	0.66 (-1.17, 2.48)	0.4800	0.12 (-0.21, 0.44)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.6.1 Completion rates of Subscale Emotional Well-Being

	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	221/ 243	90.9%	214/ 245	87.3%
Cycle 2 Day 1	189/ 243	77.8%	204/ 244	83.6%
Cycle 3 Day 1	179/ 241	74.3%	205/ 236	86.9%
Cycle 4 Day 1	198/ 240	82.5%	203/ 234	86.8%
Cycle 5 Day 1	197/ 240	82.1%	188/ 233	80.7%
Cycle 6 Day 1	195/ 239	81.6%	167/ 233	71.7%
Cycle 7 Day 1	197/ 236	83.5%	167/ 229	72.9%
Cycle 8 Day 1	197/ 234	84.2%	157/ 226	69.5%
Cycle 9 Day 1	179/ 227	78.9%	129/ 220	58.6%
Cycle 10 Day 1	171/ 221	77.4%	120/ 214	56.1%
Cycle 11 Day 1	154/ 209	73.7%	105/ 199	52.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	181/ 243	74.5%	177/ 245	72.2%
Follow up 1	96		90	
Follow up 2	38		37	
Follow up 3	39		40	
Follow up 4	21		20	
Follow up 5	6		6	
Follow up 6	4		2	

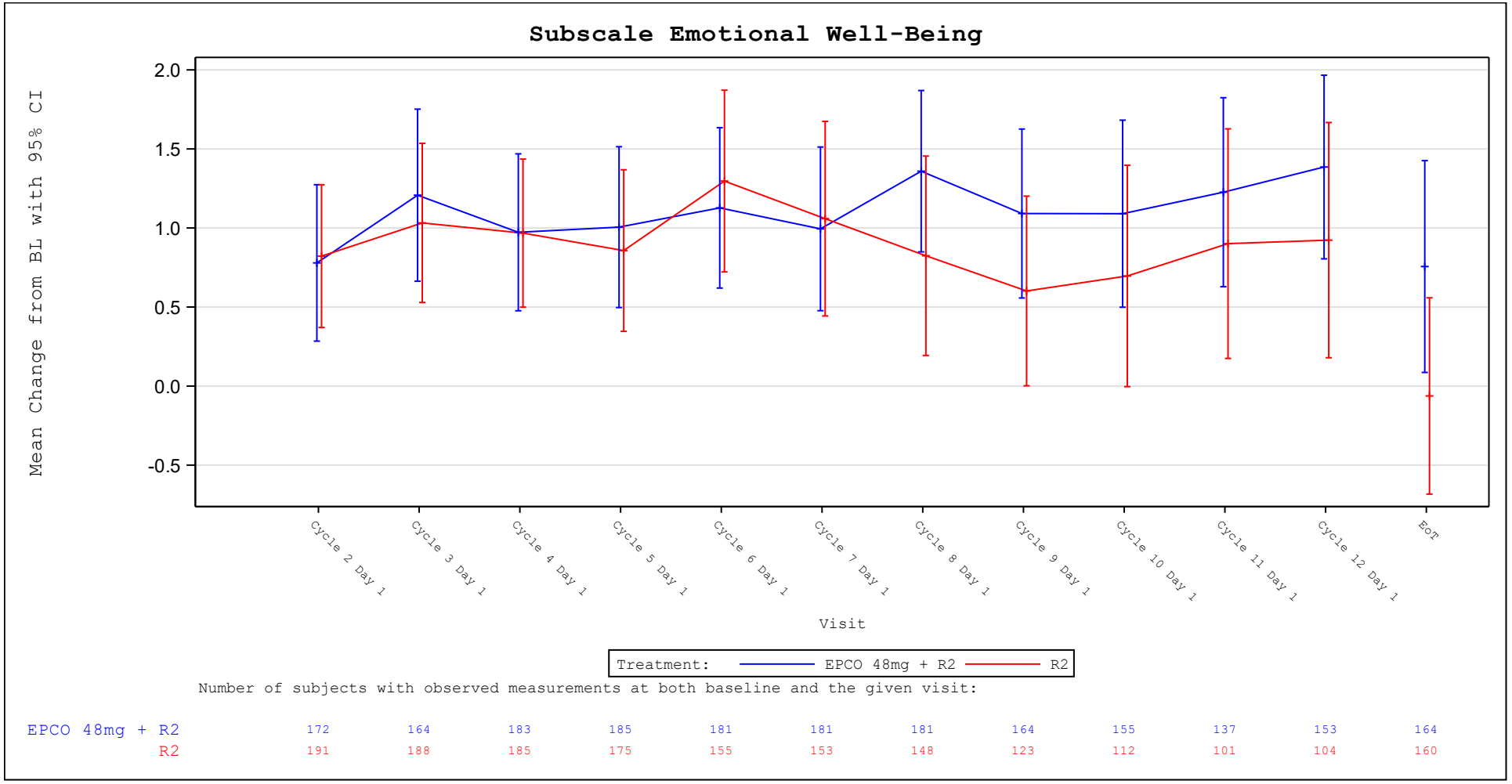
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.6.2 Summary statistics and change from baseline of Subscale Emotional Well-Being

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	221	18.16 (4.20)	0	-	214	18.10 (4.36)	0	-
Cycle 2 Day 1	189	18.92 (3.92)	172	0.78 (3.29)	204	18.96 (3.82)	191	0.82 (3.16)
Cycle 3 Day 1	179	19.32 (3.67)	164	1.21 (3.53)	205	19.06 (3.69)	188	1.03 (3.50)
Cycle 4 Day 1	198	19.41 (3.73)	183	0.97 (3.40)	203	19.11 (3.79)	185	0.97 (3.23)
Cycle 5 Day 1	197	19.16 (3.86)	185	1.01 (3.51)	188	18.89 (4.07)	175	0.86 (3.43)
Cycle 6 Day 1	195	19.45 (3.53)	181	1.13 (3.46)	167	19.37 (3.57)	155	1.30 (3.62)
Cycle 7 Day 1	197	19.37 (3.93)	181	0.99 (3.53)	167	19.16 (3.76)	153	1.06 (3.85)
Cycle 8 Day 1	197	19.55 (3.75)	181	1.36 (3.48)	157	19.08 (3.65)	148	0.82 (3.88)
Cycle 9 Day 1	179	19.47 (3.71)	164	1.09 (3.47)	129	19.26 (3.85)	123	0.60 (3.36)
Cycle 10 Day 1	171	19.24 (3.76)	155	1.09 (3.73)	120	18.98 (4.10)	112	0.70 (3.74)
Cycle 11 Day 1	154	19.25 (3.66)	137	1.23 (3.54)	105	19.34 (3.84)	101	0.90 (3.68)
Cycle 12 Day 1	167	19.44 (3.52)	153	1.39 (3.64)	107	19.16 (3.89)	104	0.92 (3.83)
End of Treatment	181	18.76 (4.21)	164	0.76 (4.34)	177	17.77 (4.28)	160	-0.06 (3.98)
Follow up 1	96	19.16 (4.25)	89	0.97 (3.95)	90	18.59 (4.15)	81	0.89 (4.04)
Follow up 2	38	19.68 (3.79)	35	1.66 (3.55)	37	18.22 (3.52)	32	0.78 (4.70)
Follow up 3	39	18.62 (4.45)	36	0.53 (4.20)	40	18.08 (4.80)	36	0.08 (4.78)
Follow up 4	21	20.95 (3.37)	19	1.79 (2.88)	20	18.85 (5.37)	20	1.65 (4.39)
Follow up 5	6	20.83 (3.13)	5	2.20 (1.30)	6	21.83 (2.14)	4	3.50 (5.74)
Follow up 6	4	22.50 (1.29)	3	3.33 (4.16)	2	16.50 (9.19)	2	1.50 (6.36)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.6.3 Graphical summary of change from baseline of Subscale Emotional Well-Being



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	172	164	183	185	181	181	181	164	155	137	153	164
R2	191	188	185	175	155	153	148	123	112	101	104	160

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.6.4 MMRM Analysis of change from baseline of Subscale Emotional Well-Being

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		0.68 (0.23)		0.75 (0.23)	-0.07 (-0.62, 0.49)	0.8114	-0.02 (-0.21, 0.17)
Cycle 3 Day 1		1.04 (0.24)		0.83 (0.23)	0.21 (-0.37, 0.80)	0.4688	0.06 (-0.13, 0.25)
Cycle 4 Day 1		0.91 (0.23)		0.96 (0.23)	-0.05 (-0.62, 0.52)	0.8663	-0.01 (-0.20, 0.18)
Cycle 5 Day 1		0.87 (0.24)		0.58 (0.24)	0.29 (-0.31, 0.89)	0.3385	0.08 (-0.11, 0.27)
Cycle 6 Day 1		1.08 (0.24)		1.04 (0.25)	0.05 (-0.56, 0.65)	0.8802	0.01 (-0.18, 0.20)
Cycle 7 Day 1		0.94 (0.25)		0.58 (0.27)	0.37 (-0.29, 1.02)	0.2743	0.10 (-0.09, 0.29)
Cycle 8 Day 1		1.21 (0.25)		0.45 (0.26)	0.76 (0.12, 1.40)	0.0199	0.20 (0.01, 0.39)
Cycle 9 Day 1		0.98 (0.25)		0.58 (0.27)	0.40 (-0.25, 1.04)	0.2285	0.11 (-0.08, 0.30)
Cycle 10 Day 1		0.80 (0.26)		0.41 (0.28)	0.39 (-0.30, 1.09)	0.2661	0.10 (-0.09, 0.29)
Cycle 11 Day 1		0.96 (0.26)		0.73 (0.28)	0.23 (-0.45, 0.91)	0.5108	0.06 (-0.13, 0.25)
Cycle 12 Day 1		0.94 (0.26)		0.24 (0.29)	0.70 (-0.00, 1.39)	0.0506	0.17 (-0.02, 0.36)
End of Treatment		0.60 (0.29)		-0.11 (0.29)	0.71 (-0.04, 1.46)	0.0620	0.17 (-0.02, 0.36)
OVERALL	219	0.83 (0.20)	207	0.65 (0.20)	0.18 (-0.29, 0.64)	0.4580	0.06 (-0.13, 0.25)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.6.4.S MMRM Analysis of change from baseline of Subscale Emotional Well-Being - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	EPCO 48mg + R2 (N=243) Baseline Mean (SD)	EPCO 48mg + R2 (N=243) Change from BL n*	EPCO 48mg + R2 (N=243) Change from BL LSMean (SE)	R2 (N=245) Baseline n	R2 (N=245) Baseline Mean (SD)	R2 (N=245) Change from BL n*	R2 (N=245) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.1233
<65	143	18.15 (4.22)	142	0.96 (0.34)	127	18.19 (4.56)	121	-0.18 (0.37)	1.13 (0.15, 2.11)	0.0240	0.28 (0.04, 0.52)	
>=65	78	18.18 (4.20)	77	0.20 (0.42)	87	17.97 (4.07)	86	0.25 (0.40)	-0.04 (-1.19, 1.10)	0.9397	-0.01 (-0.32, 0.30)	
Sex												0.5992
Male	123	18.41 (4.08)	122	0.86 (0.32)	123	18.35 (4.44)	118	-0.02 (0.33)	0.87 (-0.04, 1.78)	0.0595	0.24 (-0.01, 0.50)	
Female	98	17.85 (4.35)	97	0.36 (0.44)	91	17.76 (4.24)	89	-0.10 (0.45)	0.46 (-0.77, 1.70)	0.4590	0.11 (-0.18, 0.40)	
Disease Status 2L												0.6005
2L: progression of disease <= 2 years	56	18.21 (4.05)	55	0.79 (0.46)	53	17.15 (5.68)	49	0.00 (0.49)	0.79 (-0.55, 2.12)	0.2457	0.23 (-0.16, 0.61)	
2L: progression of disease > 2 years	87	18.30 (4.44)	86	0.21 (0.44)	89	18.84 (3.92)	87	-0.10 (0.43)	0.31 (-0.91, 1.53)	0.6187	0.08 (-0.22, 0.37)	
Disease Status 3L+												NE
3L+: < 6 months	19	18.84 (3.69)	19	NE	18	18.39 (3.65)	17	NE	NE		NE	
3L+: >= 6 months	59	17.69 (4.19)	59	0.80 (0.56)	54	17.70 (3.60)	54	0.42 (0.58)	0.38 (-1.23, 1.98)	0.6433	0.09 (-0.28, 0.46)	
Region												0.2071
US/Western Europe	50	17.38 (5.12)	50	1.32 (0.52)	53	18.70 (3.42)	52	-0.26 (0.52)	1.58 (0.11, 3.04)	0.0351	0.42 (0.03, 0.81)	
Rest of world	171	18.39 (3.88)	169	0.48 (0.31)	161	17.90 (4.62)	155	-0.01 (0.32)	0.49 (-0.38, 1.36)	0.2704	0.12 (-0.10, 0.34)	
Number of prior anti-lymphoma therapies												0.4588
2L	143	18.27 (4.28)	141	0.42 (0.32)	142	18.21 (4.71)	136	-0.04 (0.33)	0.45 (-0.46, 1.36)	0.3277	0.12 (-0.12, 0.35)	
3L+	78	17.97 (4.08)	78	1.07 (0.48)	72	17.88 (3.60)	71	-0.00 (0.50)	1.07 (-0.30, 2.43)	0.1251	0.25 (-0.07, 0.57)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.7.1 Completion rates of Subscale Functional Well-Being

	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	221/ 243	90.9%	214/ 245	87.3%
Cycle 2 Day 1	189/ 243	77.8%	204/ 244	83.6%
Cycle 3 Day 1	179/ 241	74.3%	205/ 236	86.9%
Cycle 4 Day 1	198/ 240	82.5%	203/ 234	86.8%
Cycle 5 Day 1	197/ 240	82.1%	188/ 233	80.7%
Cycle 6 Day 1	195/ 239	81.6%	167/ 233	71.7%
Cycle 7 Day 1	197/ 236	83.5%	167/ 229	72.9%
Cycle 8 Day 1	197/ 234	84.2%	157/ 226	69.5%
Cycle 9 Day 1	179/ 227	78.9%	129/ 220	58.6%
Cycle 10 Day 1	171/ 221	77.4%	120/ 214	56.1%
Cycle 11 Day 1	154/ 209	73.7%	105/ 199	52.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	181/ 243	74.5%	177/ 245	72.2%
Follow up 1	96		90	
Follow up 2	38		37	
Follow up 3	39		40	
Follow up 4	21		20	
Follow up 5	6		6	
Follow up 6	4		2	

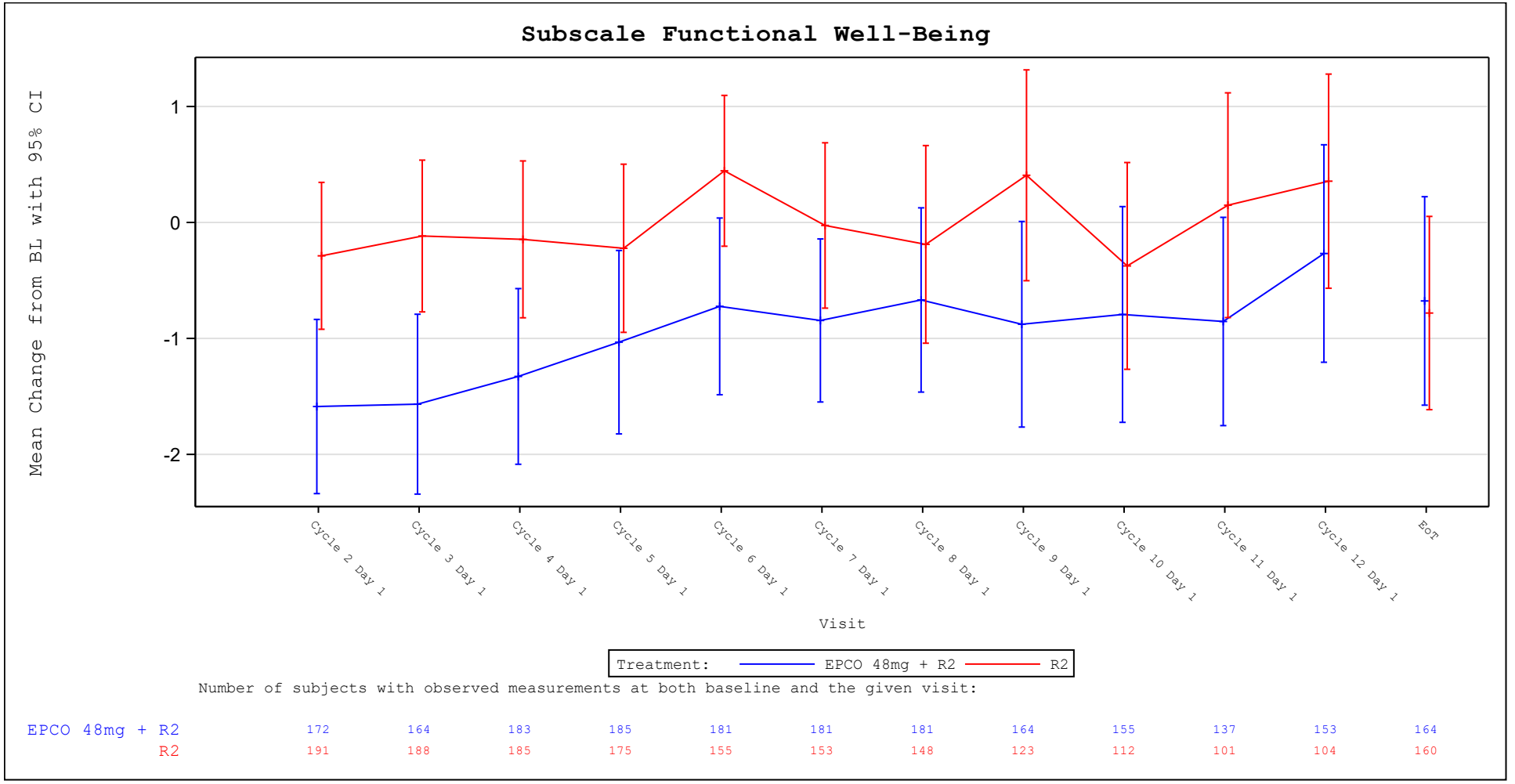
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.7.2 Summary statistics and change from baseline of Subscale Functional Well-Being

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	221	18.53 (5.48)	0	-	214	17.55 (5.89)	0	-
Cycle 2 Day 1	189	17.01 (5.85)	172	-1.59 (4.99)	204	17.32 (5.40)	191	-0.29 (4.44)
Cycle 3 Day 1	179	17.01 (5.69)	164	-1.57 (5.03)	205	17.49 (5.50)	188	-0.12 (4.55)
Cycle 4 Day 1	198	17.35 (5.78)	183	-1.33 (5.19)	203	17.55 (5.22)	185	-0.15 (4.66)
Cycle 5 Day 1	197	17.44 (5.75)	185	-1.03 (5.45)	188	17.39 (5.50)	175	-0.22 (4.86)
Cycle 6 Day 1	195	17.78 (5.82)	181	-0.72 (5.19)	167	18.31 (5.21)	155	0.45 (4.10)
Cycle 7 Day 1	197	17.87 (5.68)	181	-0.85 (4.79)	167	17.82 (5.45)	153	-0.03 (4.46)
Cycle 8 Day 1	197	17.71 (5.69)	181	-0.67 (5.42)	157	17.57 (5.71)	148	-0.19 (5.25)
Cycle 9 Day 1	179	17.83 (5.81)	164	-0.88 (5.75)	129	18.53 (5.48)	123	0.41 (5.09)
Cycle 10 Day 1	171	17.62 (5.95)	155	-0.79 (5.86)	120	17.79 (5.65)	112	-0.38 (4.76)
Cycle 11 Day 1	154	17.46 (5.97)	137	-0.85 (5.31)	105	18.50 (5.55)	101	0.15 (4.91)
Cycle 12 Day 1	167	17.79 (5.83)	153	-0.27 (5.87)	107	18.37 (5.77)	104	0.36 (4.75)
End of Treatment	181	17.41 (5.98)	164	-0.68 (5.83)	177	16.72 (5.83)	160	-0.78 (5.34)
Follow up 1	96	17.86 (6.13)	89	-0.27 (6.31)	90	17.33 (4.86)	81	0.53 (6.10)
Follow up 2	38	19.66 (5.35)	35	1.03 (5.80)	37	18.03 (5.06)	32	1.38 (6.99)
Follow up 3	39	18.74 (6.17)	36	0.81 (6.02)	40	17.78 (5.13)	36	-0.33 (7.26)
Follow up 4	21	21.24 (4.81)	19	2.47 (5.76)	20	18.90 (6.04)	20	1.90 (6.59)
Follow up 5	6	21.00 (4.15)	5	2.60 (2.70)	6	20.00 (4.94)	4	2.25 (10.08)
Follow up 6	4	24.00 (3.56)	3	0.67 (1.15)	2	13.50 (3.54)	2	-3.00 (1.41)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.7.3 Graphical summary of change from baseline of Subscale Functional Well-Being



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	172	164	183	185	181	181	181	164	155	137	153	164
R2	191	188	185	175	155	153	148	123	112	101	104	160

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.7.4 MMRM Analysis of change from baseline of Subscale Functional Well-Being

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		-1.32 (0.35)		-0.52 (0.34)	-0.80 (-1.65, 0.04)	0.0633	-0.16 (-0.35, 0.03)
Cycle 3 Day 1		-1.38 (0.36)		-0.49 (0.35)	-0.89 (-1.76, -0.02)	0.0445	-0.17 (-0.36, 0.02)
Cycle 4 Day 1		-1.17 (0.35)		-0.40 (0.35)	-0.76 (-1.63, 0.10)	0.0834	-0.15 (-0.34, 0.04)
Cycle 5 Day 1		-0.98 (0.36)		-0.53 (0.37)	-0.45 (-1.37, 0.46)	0.3306	-0.08 (-0.27, 0.11)
Cycle 6 Day 1		-0.66 (0.35)		0.13 (0.36)	-0.79 (-1.67, 0.09)	0.0770	-0.15 (-0.34, 0.04)
Cycle 7 Day 1		-0.63 (0.35)		-0.39 (0.37)	-0.24 (-1.13, 0.65)	0.6004	-0.05 (-0.24, 0.14)
Cycle 8 Day 1		-0.59 (0.38)		-0.61 (0.40)	0.02 (-0.96, 1.00)	0.9693	0.00 (-0.19, 0.19)
Cycle 9 Day 1		-0.73 (0.39)		-0.19 (0.42)	-0.54 (-1.56, 0.48)	0.3022	-0.09 (-0.28, 0.10)
Cycle 10 Day 1		-0.86 (0.39)		-0.73 (0.43)	-0.13 (-1.17, 0.91)	0.8081	-0.02 (-0.21, 0.17)
Cycle 11 Day 1		-0.78 (0.40)		-0.06 (0.43)	-0.72 (-1.78, 0.34)	0.1801	-0.12 (-0.31, 0.07)
Cycle 12 Day 1		-0.53 (0.40)		-0.20 (0.43)	-0.33 (-1.39, 0.73)	0.5442	-0.05 (-0.24, 0.14)
End of Treatment		-0.69 (0.40)		-0.82 (0.41)	0.12 (-0.90, 1.15)	0.8127	0.02 (-0.17, 0.21)
OVERALL	219	-1.11 (0.30)	207	-0.51 (0.31)	-0.61 (-1.31, 0.09)	0.0899	-0.14 (-0.33, 0.05)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.7.4.S MMRM Analysis of change from baseline of Subscale Functional Well-Being - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	EPCO 48mg + R2 (N=243) Baseline Mean (SD)	EPCO 48mg + R2 (N=243) Change from BL n*	EPCO 48mg + R2 (N=243) Change from BL LSMean (SE)	R2 (N=245) Baseline n	R2 (N=245) Baseline Mean (SD)	R2 (N=245) Change from BL n*	R2 (N=245) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.2332
<65	143	18.56 (5.21)	142	0.04 (0.45)	127	18.00 (5.91)	121	-0.55 (0.49)	0.59 (-0.72, 1.90)	0.3732	0.11 (-0.13, 0.35)	
>=65	78	18.47 (5.99)	77	-2.00 (0.57)	87	16.90 (5.84)	86	-1.36 (0.55)	-0.64 (-2.20, 0.92)	0.4204	-0.13 (-0.43, 0.18)	
Sex												0.0774
Male	123	18.37 (5.27)	122	-0.33 (0.48)	123	17.62 (5.67)	118	-1.26 (0.49)	0.93 (-0.42, 2.28)	0.1762	0.17 (-0.08, 0.43)	
Female	98	18.72 (5.76)	97	-1.17 (0.54)	91	17.46 (6.20)	89	-0.28 (0.55)	-0.89 (-2.41, 0.63)	0.2489	-0.17 (-0.46, 0.12)	
Disease Status 2L												0.1590
2L: progression of disease <= 2 years	56	18.38 (5.66)	55	0.26 (0.63)	53	16.32 (6.63)	49	-1.28 (0.68)	1.53 (-0.32, 3.39)	0.1031	0.32 (-0.07, 0.71)	
2L: progression of disease > 2 years	87	18.77 (5.60)	86	-1.13 (0.57)	89	18.84 (5.31)	87	-0.94 (0.56)	-0.19 (-1.77, 1.38)	0.8102	-0.04 (-0.33, 0.26)	
Disease Status 3L+												NE
3L+: < 6 months	19	18.95 (5.91)	19	NE	18	17.72 (6.29)	17	NE	NE		NE	
3L+: >= 6 months	59	18.19 (5.10)	59	-1.82 (0.71)	54	16.57 (5.62)	54	0.08 (0.73)	-1.90 (-3.93, 0.13)	0.0662	-0.35 (-0.72, 0.02)	
Region												0.7909
US/Western Europe	50	17.32 (6.13)	50	-0.21 (0.74)	53	17.96 (5.12)	52	-0.63 (0.73)	0.42 (-1.65, 2.49)	0.6867	0.08 (-0.31, 0.47)	
Rest of world	171	18.88 (5.25)	169	-0.86 (0.42)	161	17.42 (6.13)	155	-0.96 (0.43)	0.10 (-1.08, 1.29)	0.8650	0.02 (-0.20, 0.24)	
Number of prior anti-lymphoma therapies												0.5012
2L	143	18.62 (5.61)	141	-0.57 (0.42)	142	17.90 (5.94)	136	-1.06 (0.43)	0.49 (-0.70, 1.68)	0.4196	0.10 (-0.14, 0.33)	
3L+	78	18.37 (5.28)	78	-0.90 (0.68)	72	16.86 (5.77)	71	-0.60 (0.71)	-0.29 (-2.25, 1.67)	0.7691	-0.05 (-0.37, 0.27)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.8.1 Completion rates of Additional Lymphoma Score

Timepoint	EPCO 48mg + R2 (N=243)		R2 (N=245)	
	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	221/ 243	90.9%	214/ 245	87.3%
Cycle 2 Day 1	189/ 243	77.8%	204/ 244	83.6%
Cycle 3 Day 1	179/ 241	74.3%	205/ 236	86.9%
Cycle 4 Day 1	198/ 240	82.5%	203/ 234	86.8%
Cycle 5 Day 1	197/ 240	82.1%	188/ 233	80.7%
Cycle 6 Day 1	195/ 239	81.6%	167/ 233	71.7%
Cycle 7 Day 1	197/ 236	83.5%	167/ 229	72.9%
Cycle 8 Day 1	197/ 234	84.2%	157/ 226	69.5%
Cycle 9 Day 1	179/ 227	78.9%	129/ 220	58.6%
Cycle 10 Day 1	171/ 221	77.4%	120/ 214	56.1%
Cycle 11 Day 1	154/ 209	73.7%	105/ 199	52.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	181/ 243	74.5%	177/ 245	72.2%
Follow up 1	96		90	
Follow up 2	38		37	
Follow up 3	39		40	
Follow up 4	21		20	
Follow up 5	6		6	
Follow up 6	4		2	

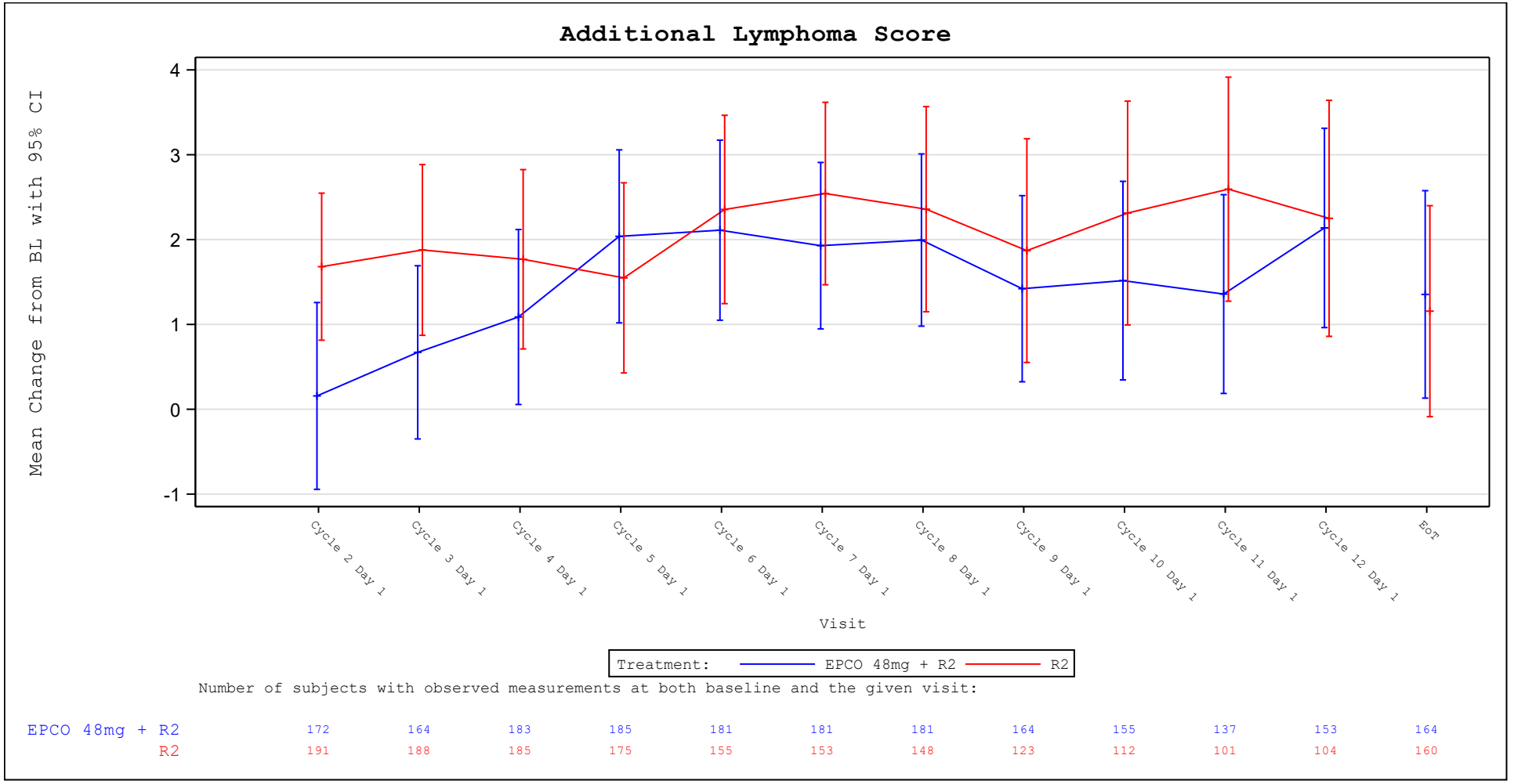
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.8.2 Summary statistics and change from baseline of Additional Lymphoma Score

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	221	46.81 (8.02)	0	-	214	46.10 (8.45)	0	-
Cycle 2 Day 1	189	47.11 (8.87)	172	0.16 (7.31)	204	47.74 (8.42)	191	1.68 (6.07)
Cycle 3 Day 1	179	47.46 (8.05)	164	0.67 (6.62)	205	47.81 (8.33)	188	1.88 (6.99)
Cycle 4 Day 1	198	48.13 (7.70)	183	1.09 (7.07)	203	48.03 (8.00)	185	1.77 (7.29)
Cycle 5 Day 1	197	49.06 (7.70)	185	2.04 (7.03)	188	47.85 (8.07)	175	1.55 (7.51)
Cycle 6 Day 1	195	49.28 (7.11)	181	2.11 (7.24)	167	48.43 (7.99)	155	2.35 (6.99)
Cycle 7 Day 1	197	49.29 (7.23)	181	1.93 (6.69)	167	48.87 (7.49)	153	2.54 (6.73)
Cycle 8 Day 1	197	49.18 (7.82)	181	1.99 (6.92)	157	48.71 (7.72)	148	2.36 (7.44)
Cycle 9 Day 1	179	48.75 (7.17)	164	1.42 (7.11)	129	48.82 (7.92)	123	1.87 (7.39)
Cycle 10 Day 1	171	48.35 (8.00)	155	1.52 (7.37)	120	48.97 (7.31)	112	2.31 (7.04)
Cycle 11 Day 1	154	48.53 (7.55)	137	1.36 (6.93)	105	49.30 (6.71)	101	2.59 (6.69)
Cycle 12 Day 1	167	48.77 (7.81)	153	2.14 (7.35)	107	49.06 (7.34)	104	2.25 (7.15)
End of Treatment	181	47.99 (8.26)	164	1.35 (7.93)	177	47.26 (8.33)	160	1.16 (7.96)
Follow up 1	96	48.86 (7.78)	89	2.21 (7.81)	90	49.88 (7.33)	81	3.80 (7.69)
Follow up 2	38	51.16 (7.27)	35	4.71 (6.67)	37	49.97 (7.46)	32	6.19 (9.54)
Follow up 3	39	49.51 (7.77)	36	3.83 (9.35)	40	48.95 (7.71)	36	3.67 (8.25)
Follow up 4	21	53.19 (6.72)	19	5.63 (6.23)	20	48.90 (10.83)	20	1.65 (8.70)
Follow up 5	6	55.50 (4.23)	5	5.60 (8.68)	6	54.50 (4.51)	4	6.75 (15.65)
Follow up 6	4	57.50 (2.38)	3	1.00 (2.00)	2	35.50 (3.54)	2	-9.50 (6.36)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.8.3 Graphical summary of change from baseline of Additional Lymphoma Score



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	172	164	183	185	181	181	181	164	155	137	153	164
R2	191	188	185	175	155	153	148	123	112	101	104	160

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.8.4 MMRM Analysis of change from baseline of Additional Lymphoma Score

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		0.07 (0.52)		1.04 (0.50)	-0.97 (-2.23, 0.29)	0.1323	-0.13 (-0.32, 0.06)
Cycle 3 Day 1		0.61 (0.51)		1.38 (0.50)	-0.77 (-2.02, 0.48)	0.2261	-0.10 (-0.29, 0.09)
Cycle 4 Day 1		0.95 (0.50)		1.60 (0.51)	-0.65 (-1.90, 0.60)	0.3067	-0.09 (-0.28, 0.10)
Cycle 5 Day 1		1.82 (0.50)		1.22 (0.52)	0.61 (-0.65, 1.87)	0.3441	0.08 (-0.11, 0.27)
Cycle 6 Day 1		1.96 (0.50)		1.82 (0.52)	0.14 (-1.12, 1.40)	0.8262	0.02 (-0.17, 0.21)
Cycle 7 Day 1		2.03 (0.48)		1.75 (0.50)	0.28 (-0.92, 1.47)	0.6475	0.04 (-0.15, 0.23)
Cycle 8 Day 1		1.96 (0.51)		1.58 (0.53)	0.38 (-0.91, 1.67)	0.5652	0.05 (-0.14, 0.24)
Cycle 9 Day 1		1.53 (0.52)		1.60 (0.55)	-0.06 (-1.40, 1.28)	0.9278	-0.01 (-0.20, 0.18)
Cycle 10 Day 1		1.50 (0.54)		1.44 (0.58)	0.06 (-1.35, 1.48)	0.9296	0.01 (-0.18, 0.20)
Cycle 11 Day 1		1.61 (0.52)		2.04 (0.56)	-0.43 (-1.78, 0.92)	0.5279	-0.06 (-0.25, 0.13)
Cycle 12 Day 1		1.55 (0.55)		1.26 (0.59)	0.29 (-1.15, 1.74)	0.6891	0.04 (-0.15, 0.23)
End of Treatment		1.33 (0.56)		1.26 (0.57)	0.07 (-1.36, 1.51)	0.9191	0.01 (-0.18, 0.20)
OVERALL	219	1.13 (0.41)	207	1.45 (0.42)	-0.32 (-1.29, 0.64)	0.5099	-0.05 (-0.24, 0.14)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.8.4.S MMRM Analysis of change from baseline of Additional Lymphoma Score - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	EPCO 48mg + R2 (N=243) Baseline Mean (SD)	EPCO 48mg + R2 (N=243) Change from BL n*	EPCO 48mg + R2 (N=243) Change from BL LSMean (SE)	R2 (N=245) Baseline n	R2 (N=245) Baseline Mean (SD)	R2 (N=245) Change from BL n*	R2 (N=245) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.7159
<65	143	46.45 (8.32)	142	2.23 (0.67)	127	46.13 (8.36)	121	2.07 (0.72)	0.16 (-1.77, 2.10)	0.8693	0.02 (-0.22, 0.26)	
>=65	78	47.47 (7.45)	77	0.26 (0.75)	87	46.05 (8.63)	86	0.62 (0.71)	-0.36 (-2.39, 1.68)	0.7301	-0.05 (-0.36, 0.25)	
Sex												0.7822
Male	123	47.32 (7.87)	122	1.30 (0.68)	123	46.66 (8.42)	118	1.02 (0.70)	0.28 (-1.64, 2.21)	0.7730	0.04 (-0.22, 0.29)	
Female	98	46.17 (8.20)	97	1.78 (0.77)	91	45.34 (8.49)	89	1.91 (0.79)	-0.12 (-2.29, 2.04)	0.9100	-0.02 (-0.30, 0.27)	
Disease Status 2L												0.4830
2L: progression of disease <= 2 years	56	46.41 (8.89)	55	2.15 (0.94)	53	44.49 (9.73)	49	1.39 (1.01)	0.76 (-1.98, 3.51)	0.5823	0.11 (-0.28, 0.49)	
2L: progression of disease > 2 years	87	47.77 (7.97)	86	0.83 (0.85)	89	47.61 (7.86)	87	1.35 (0.84)	-0.52 (-2.88, 1.84)	0.6648	-0.07 (-0.36, 0.23)	
Disease Status 3L+												NE
3L+: < 6 months	19	46.21 (7.06)	19	NE	18	44.89 (8.66)	17	NE	NE		NE	
3L+: >= 6 months	59	45.97 (7.56)	59	0.82 (1.00)	54	45.59 (7.78)	54	2.01 (1.03)	-1.20 (-4.04, 1.65)	0.4065	-0.16 (-0.53, 0.21)	
Region												0.6987
US/Western Europe	50	45.30 (9.17)	50	1.17 (1.09)	53	45.81 (7.48)	52	1.58 (1.08)	-0.41 (-3.46, 2.64)	0.7896	-0.05 (-0.44, 0.34)	
Rest of world	171	47.25 (7.63)	169	1.54 (0.58)	161	46.19 (8.77)	155	1.28 (0.60)	0.27 (-1.38, 1.91)	0.7507	0.04 (-0.18, 0.25)	
Number of prior anti-lymphoma therapies												0.9714
2L	143	47.24 (8.34)	141	1.29 (0.63)	142	46.44 (8.70)	136	1.27 (0.64)	0.02 (-1.74, 1.78)	0.9822	0.00 (-0.23, 0.24)	
3L+	78	46.03 (7.40)	78	1.91 (0.88)	72	45.42 (7.95)	71	1.83 (0.92)	0.08 (-2.43, 2.58)	0.9525	0.01 (-0.31, 0.33)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.9.1 Completion rates of FACT-Lymphoma Trial Outcome Index (TOI)

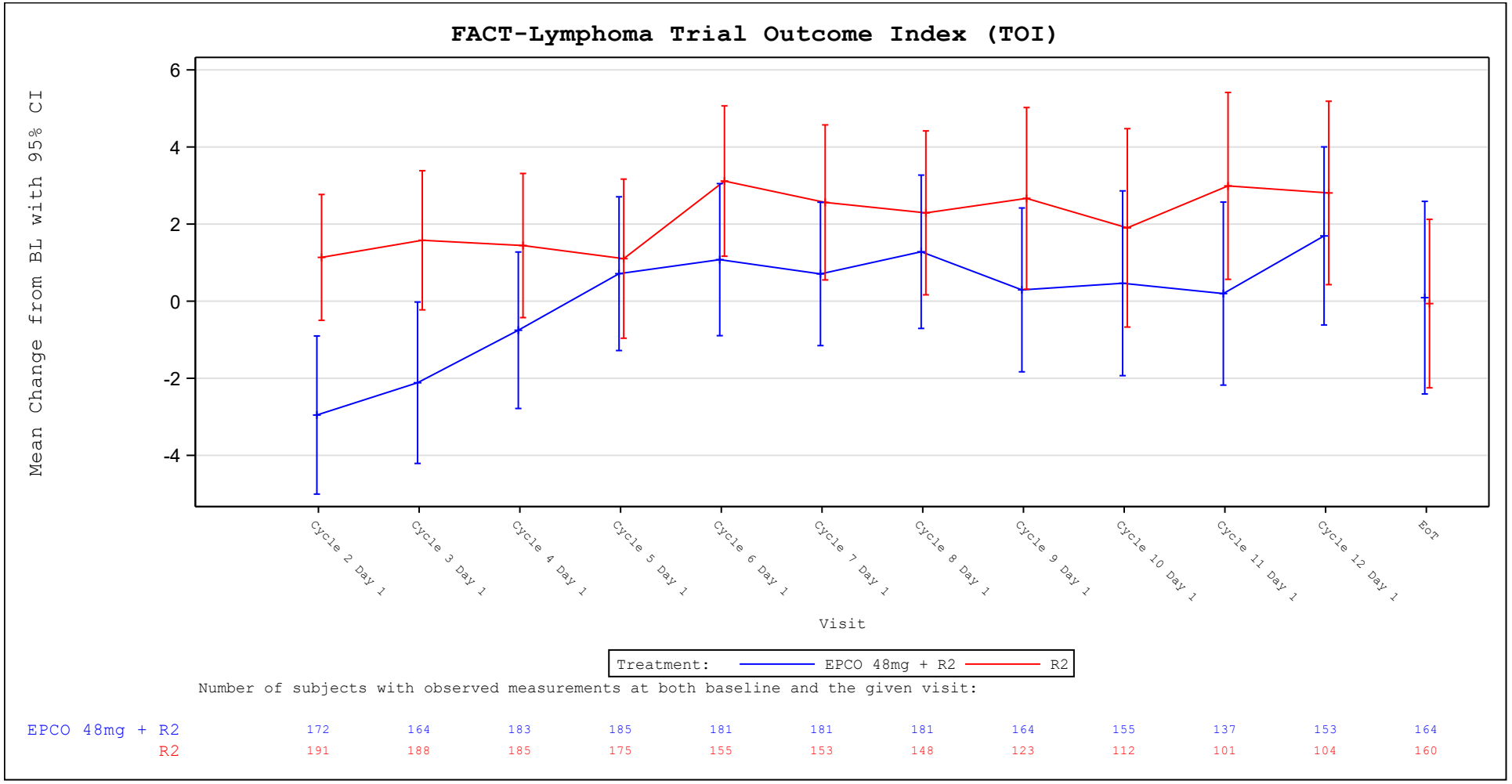
	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	221/ 243	90.9%	214/ 245	87.3%
Cycle 2 Day 1	189/ 243	77.8%	204/ 244	83.6%
Cycle 3 Day 1	179/ 241	74.3%	205/ 236	86.9%
Cycle 4 Day 1	198/ 240	82.5%	203/ 234	86.8%
Cycle 5 Day 1	197/ 240	82.1%	188/ 233	80.7%
Cycle 6 Day 1	195/ 239	81.6%	167/ 233	71.7%
Cycle 7 Day 1	197/ 236	83.5%	167/ 229	72.9%
Cycle 8 Day 1	197/ 234	84.2%	157/ 226	69.5%
Cycle 9 Day 1	179/ 227	78.9%	129/ 220	58.6%
Cycle 10 Day 1	171/ 221	77.4%	120/ 214	56.1%
Cycle 11 Day 1	154/ 209	73.7%	105/ 199	52.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	181/ 243	74.5%	177/ 245	72.2%
Follow up 1	96		90	
Follow up 2	38		37	
Follow up 3	39		40	
Follow up 4	21		20	
Follow up 5	6		6	
Follow up 6	4		2	

n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.9.2 Summary statistics and change from baseline of FACT-Lymphoma Trial Outcome Index (TOI)

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	221	88.73 (14.87)	0	-	214	86.50 (16.24)	0	-
Cycle 2 Day 1	189	85.95 (17.31)	172	-2.95 (13.63)	204	87.72 (16.05)	191	1.14 (11.43)
Cycle 3 Day 1	179	86.62 (16.15)	164	-2.12 (13.58)	205	88.12 (15.79)	188	1.58 (12.55)
Cycle 4 Day 1	198	88.40 (15.73)	183	-0.75 (13.92)	203	88.46 (15.23)	185	1.44 (12.89)
Cycle 5 Day 1	197	89.81 (15.54)	185	0.71 (13.75)	188	88.10 (16.10)	175	1.10 (13.83)
Cycle 6 Day 1	195	90.30 (15.16)	181	1.08 (13.45)	167	90.01 (15.22)	155	3.12 (12.29)
Cycle 7 Day 1	197	90.43 (14.95)	181	0.71 (12.68)	167	89.93 (15.45)	153	2.56 (12.59)
Cycle 8 Day 1	197	90.40 (15.95)	181	1.28 (13.56)	157	89.58 (15.56)	148	2.29 (13.09)
Cycle 9 Day 1	179	89.93 (14.93)	164	0.29 (13.78)	129	91.16 (15.48)	123	2.67 (13.20)
Cycle 10 Day 1	171	89.09 (16.40)	155	0.46 (15.10)	120	89.96 (15.29)	112	1.90 (13.74)
Cycle 11 Day 1	154	89.30 (16.07)	137	0.20 (14.05)	105	91.11 (14.38)	101	2.99 (12.28)
Cycle 12 Day 1	167	89.68 (15.82)	153	1.69 (14.46)	107	90.72 (14.93)	104	2.81 (12.23)
End of Treatment	181	88.07 (17.29)	164	0.09 (16.20)	177	86.41 (16.85)	160	-0.06 (14.00)
Follow up 1	96	90.26 (16.54)	89	1.92 (16.43)	90	91.52 (13.43)	81	5.72 (14.71)
Follow up 2	38	95.74 (14.85)	35	7.34 (13.72)	37	92.05 (13.89)	32	9.31 (19.67)
Follow up 3	39	92.31 (16.06)	36	5.42 (16.93)	40	90.63 (15.32)	36	4.00 (18.61)
Follow up 4	21	100.52 (12.65)	19	9.84 (13.39)	20	91.73 (20.41)	20	4.23 (19.54)
Follow up 5	6	101.50 (10.52)	5	8.80 (14.34)	6	101.00 (8.60)	4	11.00 (29.38)
Follow up 6	4	108.75 (5.12)	3	1.33 (2.08)	2	63.50 (7.78)	2	-20.00 (12.73)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.



Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.9.4 MMRM Analysis of change from baseline of FACT-Lymphoma Trial Outcome Index (TOI)

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		-2.85 (0.97)		0.02 (0.95)	-2.87 (-5.22, -0.52)	0.0168	-0.20 (-0.39, -0.01)
Cycle 3 Day 1		-2.20 (0.99)		0.66 (0.97)	-2.86 (-5.26, -0.45)	0.0200	-0.20 (-0.39, -0.01)
Cycle 4 Day 1		-0.91 (0.97)		1.03 (0.98)	-1.94 (-4.33, 0.45)	0.1113	-0.14 (-0.33, 0.05)
Cycle 5 Day 1		0.51 (1.00)		0.46 (1.02)	0.05 (-2.45, 2.55)	0.9687	0.00 (-0.19, 0.19)
Cycle 6 Day 1		0.78 (0.96)		2.06 (1.00)	-1.28 (-3.68, 1.12)	0.2946	-0.09 (-0.28, 0.10)
Cycle 7 Day 1		0.85 (0.96)		1.13 (1.01)	-0.29 (-2.69, 2.12)	0.8162	-0.02 (-0.21, 0.17)
Cycle 8 Day 1		1.16 (0.99)		0.87 (1.04)	0.28 (-2.24, 2.80)	0.8245	0.02 (-0.17, 0.21)
Cycle 9 Day 1		0.36 (1.02)		1.44 (1.09)	-1.08 (-3.73, 1.57)	0.4233	-0.07 (-0.26, 0.12)
Cycle 10 Day 1		-0.01 (1.10)		0.02 (1.19)	-0.03 (-2.94, 2.88)	0.9836	-0.00 (-0.19, 0.19)
Cycle 11 Day 1		0.44 (1.06)		1.87 (1.14)	-1.43 (-4.21, 1.35)	0.3121	-0.09 (-0.28, 0.10)
Cycle 12 Day 1		0.39 (1.06)		0.75 (1.15)	-0.37 (-3.16, 2.43)	0.7972	-0.02 (-0.21, 0.17)
End of Treatment		0.08 (1.11)		0.16 (1.14)	-0.08 (-2.93, 2.77)	0.9569	-0.00 (-0.19, 0.19)
OVERALL	219	-1.06 (0.82)	207	0.47 (0.84)	-1.53 (-3.45, 0.39)	0.1174	-0.13 (-0.32, 0.06)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.9.4.S MMRM Analysis of change from baseline of FACT-Lymphoma Trial Outcome Index (TOI) - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	Baseline Mean (SD)	Change from BL n*	Change from BL LSMean (SE)	R2 (N=245) Baseline n	Baseline Mean (SD)	Change from BL n*	Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.1210
<65	143	88.10 (14.93)	142	2.92 (1.26)	127	86.93 (16.03)	121	1.46 (1.36)	1.47 (-2.19, 5.12)	0.4298	0.10 (-0.15, 0.34)	
>=65	78	89.87 (14.79)	77	-4.14 (1.61)	87	85.87 (16.60)	86	-1.12 (1.53)	-3.02 (-7.41, 1.37)	0.1761	-0.21 (-0.52, 0.10)	
Sex												0.3502
Male	123	89.46 (14.84)	122	0.73 (1.31)	123	87.36 (15.90)	118	-0.51 (1.35)	1.24 (-2.46, 4.94)	0.5102	0.08 (-0.17, 0.34)	
Female	98	87.82 (14.93)	97	-0.03 (1.57)	91	85.34 (16.70)	89	1.47 (1.62)	-1.50 (-5.96, 2.95)	0.5061	-0.10 (-0.39, 0.19)	
Disease Status 2L												0.1577
2L: progression of disease <= 2 years	56	87.43 (16.48)	55	3.23 (1.72)	53	82.77 (18.99)	49	-0.25 (1.85)	3.48 (-1.54, 8.50)	0.1724	0.27 (-0.12, 0.66)	
2L: progression of disease > 2 years	87	90.56 (15.26)	86	-1.43 (1.65)	89	90.01 (15.04)	87	-0.05 (1.64)	-1.38 (-5.97, 3.22)	0.5544	-0.09 (-0.39, 0.21)	
Disease Status 3L+												NE
3L+: < 6 months	19	88.16 (14.23)	19	NE	18	84.39 (14.98)	17	NE	NE		NE	
3L+: >= 6 months	59	87.44 (12.82)	59	-2.01 (2.10)	54	85.07 (14.83)	54	2.38 (2.17)	-4.39 (-10.39, 1.62)	0.1501	-0.27 (-0.64, 0.10)	
Region												0.8098
US/Western Europe	50	85.98 (17.64)	50	-0.94 (2.21)	53	86.77 (14.40)	52	-0.44 (2.18)	-0.50 (-6.65, 5.66)	0.8732	-0.03 (-0.42, 0.36)	
Rest of world	171	89.53 (13.91)	169	0.73 (1.13)	161	86.41 (16.84)	155	0.38 (1.18)	0.35 (-2.87, 3.56)	0.8318	0.02 (-0.19, 0.24)	
Number of prior anti-lymphoma therapies												0.7329
2L	143	89.34 (15.77)	141	0.29 (1.22)	142	87.31 (16.93)	136	-0.22 (1.25)	0.51 (-2.92, 3.94)	0.7703	0.04 (-0.20, 0.27)	
3L+	78	87.62 (13.09)	78	0.60 (1.82)	72	84.90 (14.76)	71	1.17 (1.90)	-0.57 (-5.77, 4.64)	0.8295	-0.04 (-0.36, 0.29)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g > 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.10.1 Completion rates of PGI-Change

Timepoint	EPCO 48mg + R2 (N=243)		R2 (N=245)	
	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Cycle 2 Day 1	178/ 243	73.3%	196/ 244	80.3%
Cycle 3 Day 1	173/ 241	71.8%	200/ 236	84.7%
Cycle 4 Day 1	192/ 240	80.0%	194/ 234	82.9%
Cycle 5 Day 1	192/ 240	80.0%	182/ 233	78.1%
Cycle 6 Day 1	192/ 239	80.3%	161/ 233	69.1%
Cycle 7 Day 1	194/ 236	82.2%	164/ 229	71.6%
Cycle 8 Day 1	193/ 234	82.5%	156/ 226	69.0%
Cycle 9 Day 1	177/ 227	78.0%	128/ 220	58.2%
Cycle 10 Day 1	170/ 221	76.9%	118/ 214	55.1%
Cycle 11 Day 1	151/ 209	72.2%	103/ 199	51.8%
Cycle 12 Day 1	166/ 205	81.0%	106/ 189	56.1%
End of Treatment	179/ 243	73.7%	172/ 245	70.2%
Follow up 1	96		87	
Follow up 2	37		37	
Follow up 3	37		38	
Follow up 4	20		20	
Follow up 5	6		6	
Follow up 6	3		2	

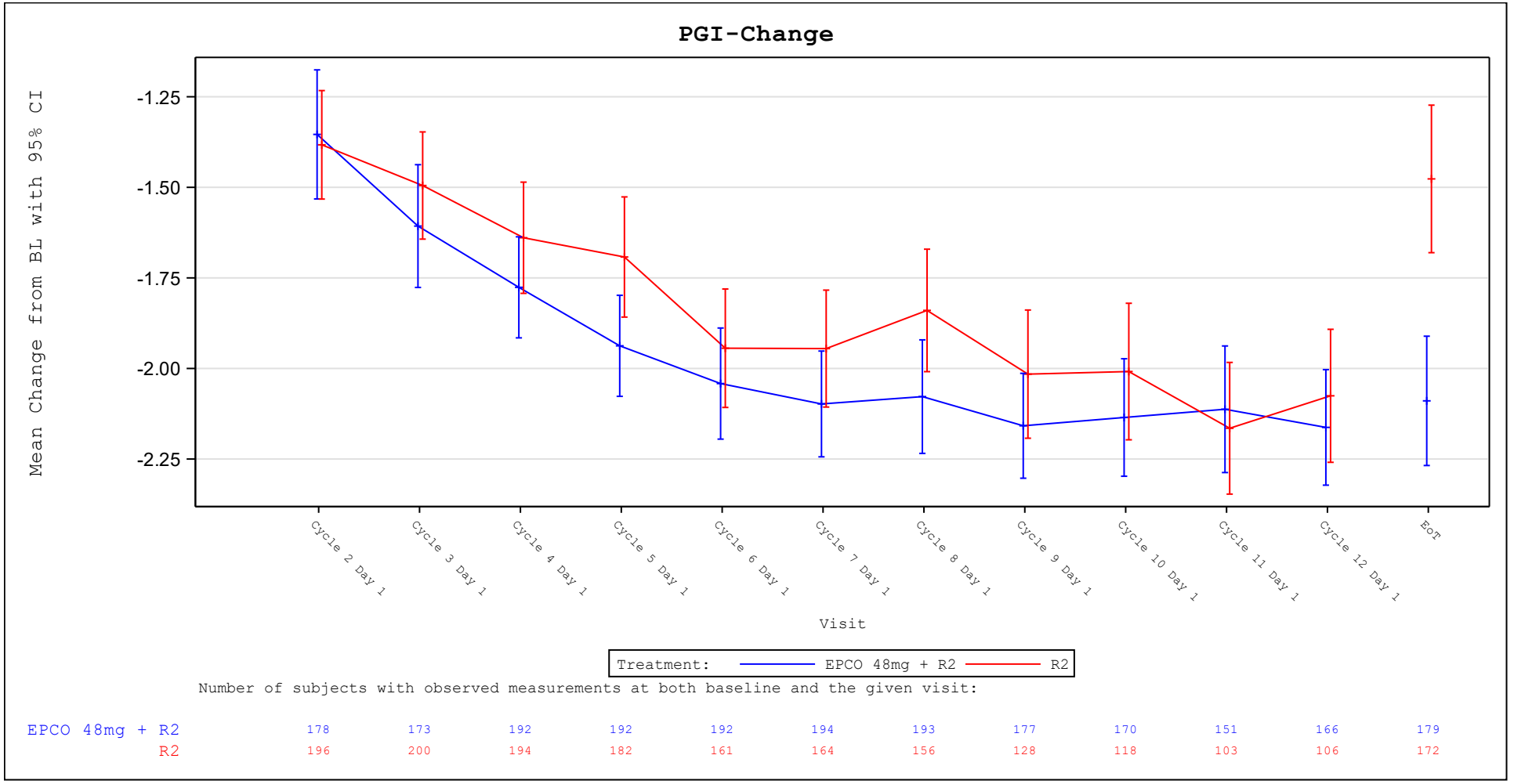
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.10.2 Summary statistics and change from baseline of PGI-Change

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Cycle 2 Day 1	178	-1.35 (1.20)	178	-1.35 (1.20)	196	-1.38 (1.06)	196	-1.38 (1.06)
Cycle 3 Day 1	173	-1.61 (1.13)	173	-1.61 (1.13)	200	-1.50 (1.06)	200	-1.50 (1.06)
Cycle 4 Day 1	192	-1.78 (0.98)	192	-1.78 (0.98)	194	-1.64 (1.08)	194	-1.64 (1.08)
Cycle 5 Day 1	192	-1.94 (0.98)	192	-1.94 (0.98)	182	-1.69 (1.13)	182	-1.69 (1.13)
Cycle 6 Day 1	192	-2.04 (1.08)	192	-2.04 (1.08)	161	-1.94 (1.05)	161	-1.94 (1.05)
Cycle 7 Day 1	194	-2.10 (1.03)	194	-2.10 (1.03)	164	-1.95 (1.05)	164	-1.95 (1.05)
Cycle 8 Day 1	193	-2.08 (1.10)	193	-2.08 (1.10)	156	-1.84 (1.07)	156	-1.84 (1.07)
Cycle 9 Day 1	177	-2.16 (0.98)	177	-2.16 (0.98)	128	-2.02 (1.01)	128	-2.02 (1.01)
Cycle 10 Day 1	170	-2.14 (1.07)	170	-2.14 (1.07)	118	-2.01 (1.03)	118	-2.01 (1.03)
Cycle 11 Day 1	151	-2.11 (1.09)	151	-2.11 (1.09)	103	-2.17 (0.93)	103	-2.17 (0.93)
Cycle 12 Day 1	166	-2.16 (1.04)	166	-2.16 (1.04)	106	-2.08 (0.95)	106	-2.08 (0.95)
End of Treatment	179	-2.09 (1.21)	179	-2.09 (1.21)	172	-1.48 (1.35)	172	-1.48 (1.35)
Follow up 1	96	-2.24 (0.96)	96	-2.24 (0.96)	87	-1.87 (1.15)	87	-1.87 (1.15)
Follow up 2	37	-2.35 (0.95)	37	-2.35 (0.95)	37	-1.41 (1.55)	37	-1.41 (1.55)
Follow up 3	37	-2.05 (1.15)	37	-2.05 (1.15)	38	-1.55 (1.50)	38	-1.55 (1.50)
Follow up 4	20	-2.65 (0.59)	20	-2.65 (0.59)	20	-1.70 (1.38)	20	-1.70 (1.38)
Follow up 5	6	-2.83 (0.41)	6	-2.83 (0.41)	6	-1.50 (1.64)	6	-1.50 (1.64)
Follow up 6	3	-3.00 (0.00)	3	-3.00 (0.00)	2	-2.00 (1.41)	2	-2.00 (1.41)

N1 and N2 describe number of patients with non-missing value at the respective timepoint.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.10.3 Graphical summary of change from baseline of PGI-Change



Number of subjects with observed measurements at both baseline and the given visit:

	Cycle 2 Day 1	Cycle 3 Day 1	Cycle 4 Day 1	Cycle 5 Day 1	Cycle 6 Day 1	Cycle 7 Day 1	Cycle 8 Day 1	Cycle 9 Day 1	Cycle 10 Day 1	Cycle 11 Day 1	Cycle 12 Day 1	EoT
EPCO 48mg + R2	178	173	192	192	192	194	193	177	170	151	166	179
R2	196	200	194	182	161	164	156	128	118	103	106	172

Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.10.4 MMRM Analysis of change from baseline of PGI-Change

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		-1.23 (0.09)		-1.29 (0.09)	0.06 (-0.17, 0.28)	0.6223	0.04 (-0.14, 0.22)
Cycle 3 Day 1		-1.52 (0.08)		-1.41 (0.08)	-0.11 (-0.32, 0.10)	0.3144	-0.08 (-0.27, 0.10)
Cycle 4 Day 1		-1.66 (0.08)		-1.56 (0.08)	-0.10 (-0.30, 0.10)	0.3186	-0.08 (-0.26, 0.10)
Cycle 5 Day 1		-1.82 (0.08)		-1.60 (0.08)	-0.21 (-0.43, -0.00)	0.0457	-0.17 (-0.35, 0.01)
Cycle 6 Day 1		-1.96 (0.08)		-1.78 (0.09)	-0.18 (-0.39, 0.04)	0.1026	-0.14 (-0.32, 0.04)
Cycle 7 Day 1		-2.00 (0.08)		-1.72 (0.08)	-0.28 (-0.49, -0.08)	0.0072	-0.23 (-0.41, -0.04)
Cycle 8 Day 1		-2.00 (0.08)		-1.65 (0.09)	-0.35 (-0.57, -0.13)	0.0018	-0.27 (-0.45, -0.08)
Cycle 9 Day 1		-2.06 (0.08)		-1.80 (0.09)	-0.26 (-0.46, -0.05)	0.0155	-0.20 (-0.39, -0.02)
Cycle 10 Day 1		-2.01 (0.08)		-1.77 (0.09)	-0.25 (-0.47, -0.02)	0.0301	-0.19 (-0.37, -0.00)
Cycle 11 Day 1		-2.03 (0.08)		-1.93 (0.09)	-0.10 (-0.33, 0.12)	0.3592	-0.08 (-0.26, 0.10)
Cycle 12 Day 1		-2.05 (0.08)		-1.79 (0.09)	-0.26 (-0.48, -0.04)	0.0221	-0.20 (-0.38, -0.01)
End of Treatment		-2.03 (0.10)		-1.45 (0.10)	-0.58 (-0.83, -0.32)	<.0001	-0.39 (-0.57, -0.21)
OVERALL	240	-1.81 (0.06)	229	-1.55 (0.07)	-0.25 (-0.40, -0.10)	0.0013	-0.25 (-0.43, -0.07)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g < 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurement at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.10.4.S MMRM Analysis of change from baseline of PGI-Change - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	Baseline Mean (SD)	Change from BL n*	Change from BL LSMean (SE)	R2 (N=245) Baseline n	Baseline Mean (SD)	Change from BL n*	Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.1318
<65	0	-	153	-2.24 (0.11)	0	-	129	-1.49 (0.12)	-0.74 (-1.07, -0.42)	<.0001	-0.54 (-0.78, -0.30)	
>=65	0	-	87	-1.85 (0.15)	0	-	100	-1.51 (0.14)	-0.35 (-0.75, 0.06)	0.0922	-0.25 (-0.54, 0.04)	
Sex												0.1732
Male	0	-	137	-2.15 (0.12)	0	-	129	-1.42 (0.12)	-0.73 (-1.07, -0.39)	<.0001	-0.52 (-0.77, -0.28)	
Female	0	-	103	-2.04 (0.14)	0	-	100	-1.67 (0.14)	-0.38 (-0.76, 0.00)	0.0522	-0.27 (-0.55, 0.00)	
Disease Status 2L												0.1184
2L: progression of disease <= 2 years	0	-	62	-2.28 (0.18)	0	-	55	-1.22 (0.19)	-1.06 (-1.58, -0.54)	<.0001	-0.75 (-1.12, -0.37)	
2L: progression of disease > 2 years	0	-	93	-2.10 (0.14)	0	-	92	-1.55 (0.14)	-0.55 (-0.94, -0.15)	0.0066	-0.40 (-0.69, -0.11)	
Disease Status 3L+												NE
3L+: < 6 months	0	-	22	NE	0	-	21	NE	NE		NE	
3L+: >= 6 months	0	-	63	-1.95 (0.18)	0	-	61	-1.78 (0.18)	-0.17 (-0.67, 0.32)	0.4872	-0.12 (-0.48, 0.23)	
Region												0.8474
US/Western Europe	0	-	58	-1.91 (0.18)	0	-	56	-1.37 (0.19)	-0.54 (-1.06, -0.02)	0.0415	-0.38 (-0.76, -0.01)	
Rest of world	0	-	182	-2.16 (0.10)	0	-	173	-1.56 (0.11)	-0.60 (-0.89, -0.31)	<.0001	-0.43 (-0.64, -0.22)	
Number of prior anti-lymphoma therapies												0.0722
2L	0	-	155	-2.17 (0.11)	0	-	147	-1.42 (0.11)	-0.74 (-1.06, -0.43)	<.0001	-0.54 (-0.77, -0.31)	
3L+	0	-	85	-1.96 (0.15)	0	-	82	-1.70 (0.16)	-0.26 (-0.69, 0.17)	0.2327	-0.18 (-0.49, 0.12)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g < 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurement at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 3.11.1 Completion rates of PGI-Severity

	EPCO 48mg + R2 (N=243)		R2 (N=245)	
Timepoint	n/ N_ALIVE	Completion	n/ N_ALIVE	Completion
Baseline	217/ 243	89.3%	205/ 245	83.7%
Cycle 2 Day 1	185/ 243	76.1%	198/ 244	81.1%
Cycle 3 Day 1	174/ 241	72.2%	201/ 236	85.2%
Cycle 4 Day 1	194/ 240	80.8%	195/ 234	83.3%
Cycle 5 Day 1	196/ 240	81.7%	183/ 233	78.5%
Cycle 6 Day 1	194/ 239	81.2%	162/ 233	69.5%
Cycle 7 Day 1	196/ 236	83.1%	165/ 229	72.1%
Cycle 8 Day 1	193/ 234	82.5%	156/ 226	69.0%
Cycle 9 Day 1	178/ 227	78.4%	129/ 220	58.6%
Cycle 10 Day 1	170/ 221	76.9%	119/ 214	55.6%
Cycle 11 Day 1	152/ 209	72.7%	103/ 199	51.8%
Cycle 12 Day 1	167/ 205	81.5%	107/ 189	56.6%
End of Treatment	179/ 243	73.7%	174/ 245	71.0%
Follow up 1	96		87	
Follow up 2	37		37	
Follow up 3	37		39	
Follow up 4	20		20	
Follow up 5	6		6	
Follow up 6	3		2	

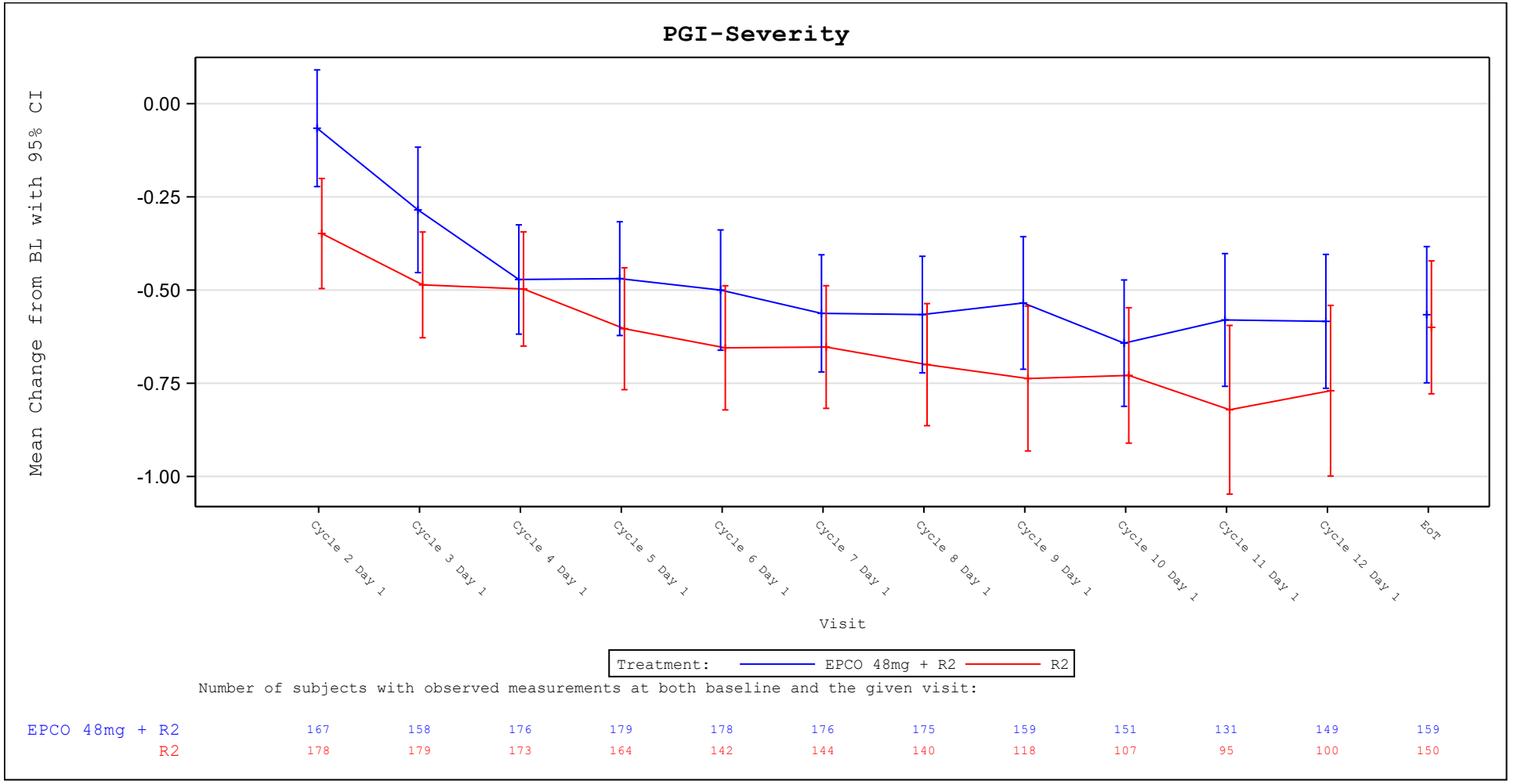
n describes number of patients with non-missing value at the respective timepoint.
N_ALIVE defines number of patients with minimum(death day, last contact day) >= analysis window beginning timepoint (baseline=day 1, cycle 2=day 2, cycle 3=day 43, ... , cycle 12=day 295). All patients included for End of Treatment.
N=Number of subjects in Intention-to-Treat Analysis Set

Table 3.11.2 Summary statistics and change from baseline of PGI-Severity

	EPCO 48mg + R2 (N=243)				R2 (N=245)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N1	Mean (SD)	N2	Mean (SD)	N1	Mean (SD)	N2	Mean (SD)
Baseline	217	2.06 (0.91)	0	-	205	2.27 (0.96)	0	-
Cycle 2 Day 1	185	2.02 (0.94)	167	-0.07 (1.02)	198	1.93 (0.85)	178	-0.35 (1.00)
Cycle 3 Day 1	174	1.75 (0.83)	158	-0.28 (1.07)	201	1.78 (0.81)	179	-0.49 (0.96)
Cycle 4 Day 1	194	1.61 (0.73)	176	-0.47 (0.99)	195	1.70 (0.81)	173	-0.50 (1.02)
Cycle 5 Day 1	196	1.56 (0.72)	179	-0.47 (1.03)	183	1.61 (0.74)	164	-0.60 (1.06)
Cycle 6 Day 1	194	1.54 (0.73)	178	-0.50 (1.09)	162	1.62 (0.80)	142	-0.65 (1.00)
Cycle 7 Day 1	196	1.47 (0.70)	176	-0.56 (1.06)	165	1.59 (0.76)	144	-0.65 (1.00)
Cycle 8 Day 1	193	1.46 (0.69)	175	-0.57 (1.05)	156	1.56 (0.73)	140	-0.70 (0.98)
Cycle 9 Day 1	178	1.50 (0.72)	159	-0.53 (1.14)	129	1.50 (0.73)	118	-0.74 (1.07)
Cycle 10 Day 1	170	1.44 (0.65)	151	-0.64 (1.05)	119	1.56 (0.74)	107	-0.73 (0.95)
Cycle 11 Day 1	152	1.44 (0.62)	131	-0.58 (1.03)	103	1.49 (0.73)	95	-0.82 (1.11)
Cycle 12 Day 1	167	1.49 (0.71)	149	-0.58 (1.11)	107	1.53 (0.79)	100	-0.77 (1.15)
End of Treatment	179	1.51 (0.82)	159	-0.57 (1.17)	174	1.72 (0.86)	150	-0.60 (1.11)
Follow up 1	96	1.29 (0.56)	86	-0.77 (0.90)	87	1.49 (0.78)	75	-0.92 (1.15)
Follow up 2	37	1.19 (0.52)	32	-0.75 (0.98)	37	1.57 (0.87)	30	-0.83 (1.32)
Follow up 3	37	1.38 (0.72)	33	-0.82 (0.77)	39	1.54 (0.94)	35	-0.86 (1.17)
Follow up 4	20	1.10 (0.31)	18	-1.00 (0.97)	20	1.65 (1.09)	20	-0.65 (1.31)
Follow up 5	6	1.17 (0.41)	5	-0.60 (0.89)	6	1.00 (0.00)	4	-0.25 (0.50)
Follow up 6	3	1.00 (0.00)	2	0.00 (0.00)	2	2.50 (0.71)	2	0.00 (0.00)

N1 describes number of patients with non-missing value at the respective timepoint. N2 describes number of patients with observed measurements at both baseline and the given visit.
N=Number of subjects in Intention-to-Treat Analysis Set, SD=Standard Deviation.

Figure 3.11.3 Graphical summary of change from baseline of PGI-Severity



Only visits with N>=5 patients in at least one treatment group are displayed.
BL=Baseline, CI=Confidence Interval, EoT=End of Treatment

Table 3.11.4 MMRM Analysis of change from baseline of PGI-Severity

Visit	EPCO 48mg + R2 (N=243) n	EPCO 48mg + R2 (N=243) LSMean (SE)	R2 (N=245) n	R2 (N=245) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Cycle 2 Day 1		-0.09 (0.07)		-0.21 (0.07)	0.12 (-0.06, 0.29)	0.1865	0.12 (-0.07, 0.31)
Cycle 3 Day 1		-0.31 (0.06)		-0.37 (0.06)	0.06 (-0.10, 0.22)	0.4623	0.07 (-0.13, 0.26)
Cycle 4 Day 1		-0.46 (0.06)		-0.39 (0.06)	-0.07 (-0.23, 0.08)	0.3600	-0.08 (-0.28, 0.11)
Cycle 5 Day 1		-0.51 (0.06)		-0.47 (0.06)	-0.04 (-0.19, 0.10)	0.5875	-0.05 (-0.24, 0.15)
Cycle 6 Day 1		-0.53 (0.06)		-0.49 (0.06)	-0.04 (-0.20, 0.12)	0.6091	-0.05 (-0.24, 0.15)
Cycle 7 Day 1		-0.61 (0.06)		-0.51 (0.06)	-0.10 (-0.25, 0.05)	0.2082	-0.11 (-0.31, 0.08)
Cycle 8 Day 1		-0.61 (0.06)		-0.55 (0.06)	-0.06 (-0.21, 0.08)	0.3963	-0.08 (-0.27, 0.12)
Cycle 9 Day 1		-0.58 (0.06)		-0.59 (0.07)	0.01 (-0.16, 0.17)	0.9403	0.01 (-0.19, 0.20)
Cycle 10 Day 1		-0.64 (0.06)		-0.51 (0.06)	-0.14 (-0.29, 0.02)	0.0812	-0.16 (-0.35, 0.04)
Cycle 11 Day 1		-0.60 (0.06)		-0.58 (0.07)	-0.02 (-0.18, 0.14)	0.7924	-0.02 (-0.22, 0.17)
Cycle 12 Day 1		-0.57 (0.06)		-0.52 (0.07)	-0.06 (-0.24, 0.12)	0.5260	-0.06 (-0.25, 0.13)
End of Treatment		-0.52 (0.07)		-0.49 (0.07)	-0.04 (-0.22, 0.14)	0.6859	-0.04 (-0.23, 0.16)
OVERALL	214	-0.48 (0.04)	198	-0.43 (0.05)	-0.05 (-0.15, 0.06)	0.3948	-0.07 (-0.26, 0.12)

Mixed-Effect Model with Repeated Measures (MMRM) analysis with stratification factors of disease status and region and treatment arm as fixed factors and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model. OVERALL results estimated with same model excluding factors for time.
Mean differences and Hedges`g < 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
N=Number of subjects in Intention-to-Treat Analysis Set, LSMean=Least Square Mean, SE=Standard Error, CI=Confidence Interval

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Intention-to-Treat Analysis Set
Table 3.11.4.S MMRM Analysis of change from baseline of PGI-Severity - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) Baseline n	Baseline Mean (SD)	Change from BL n*	Change from BL LSMean (SE)	R2 (N=245) Baseline n	Baseline Mean (SD)	Change from BL n*	Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Age (years)												0.8209
<65	139	2.06 (0.93)	137	-0.61 (0.08)	122	2.30 (0.88)	116	-0.53 (0.08)	-0.07 (-0.30, 0.15)	0.5173	-0.08 (-0.33, 0.17)	
>=65	78	2.05 (0.90)	77	-0.48 (0.11)	83	2.24 (1.08)	82	-0.45 (0.10)	-0.03 (-0.32, 0.26)	0.8327	-0.03 (-0.34, 0.28)	
Sex												0.6366
Male	121	1.99 (0.87)	119	-0.52 (0.09)	118	2.24 (0.94)	113	-0.52 (0.09)	0.00 (-0.24, 0.24)	0.9988	0.00 (-0.26, 0.26)	
Female	96	2.15 (0.96)	95	-0.60 (0.09)	87	2.32 (0.99)	85	-0.51 (0.10)	-0.09 (-0.35, 0.18)	0.5256	-0.09 (-0.39, 0.20)	
Disease Status 2L												0.0987
2L: progression of disease <= 2 years	55	2.16 (1.03)	54	-0.85 (0.13)	50	2.38 (1.01)	46	-0.45 (0.14)	-0.40 (-0.78, -0.01)	0.0423	-0.41 (-0.81, -0.01)	
2L: progression of disease > 2 years	86	1.91 (0.85)	85	-0.47 (0.09)	85	2.16 (0.91)	83	-0.46 (0.09)	-0.01 (-0.27, 0.24)	0.9156	-0.02 (-0.32, 0.29)	
Disease Status 3L+												NE
3L+: < 6 months	19	2.32 (0.89)	18	NE	18	2.50 (0.99)	17	NE	NE		NE	
3L+: >= 6 months	57	2.11 (0.88)	57	-0.41 (0.13)	52	2.27 (0.99)	52	-0.57 (0.14)	0.16 (-0.22, 0.53)	0.4015	0.16 (-0.22, 0.54)	
Region												0.8875
US/Western Europe	50	2.04 (0.99)	50	-0.56 (0.14)	51	2.24 (0.99)	50	-0.55 (0.14)	-0.01 (-0.42, 0.39)	0.9419	-0.01 (-0.41, 0.38)	
Rest of world	167	2.07 (0.89)	164	-0.55 (0.07)	154	2.29 (0.95)	148	-0.50 (0.07)	-0.05 (-0.25, 0.16)	0.6482	-0.05 (-0.27, 0.17)	
Number of prior anti-lymphoma therapies												0.0961
2L	141	2.01 (0.93)	139	-0.61 (0.08)	135	2.24 (0.95)	129	-0.47 (0.08)	-0.14 (-0.35, 0.07)	0.1972	-0.16 (-0.40, 0.08)	
3L+	76	2.16 (0.88)	75	-0.43 (0.11)	70	2.33 (0.99)	69	-0.62 (0.12)	0.19 (-0.14, 0.52)	0.2562	0.19 (-0.14, 0.52)	

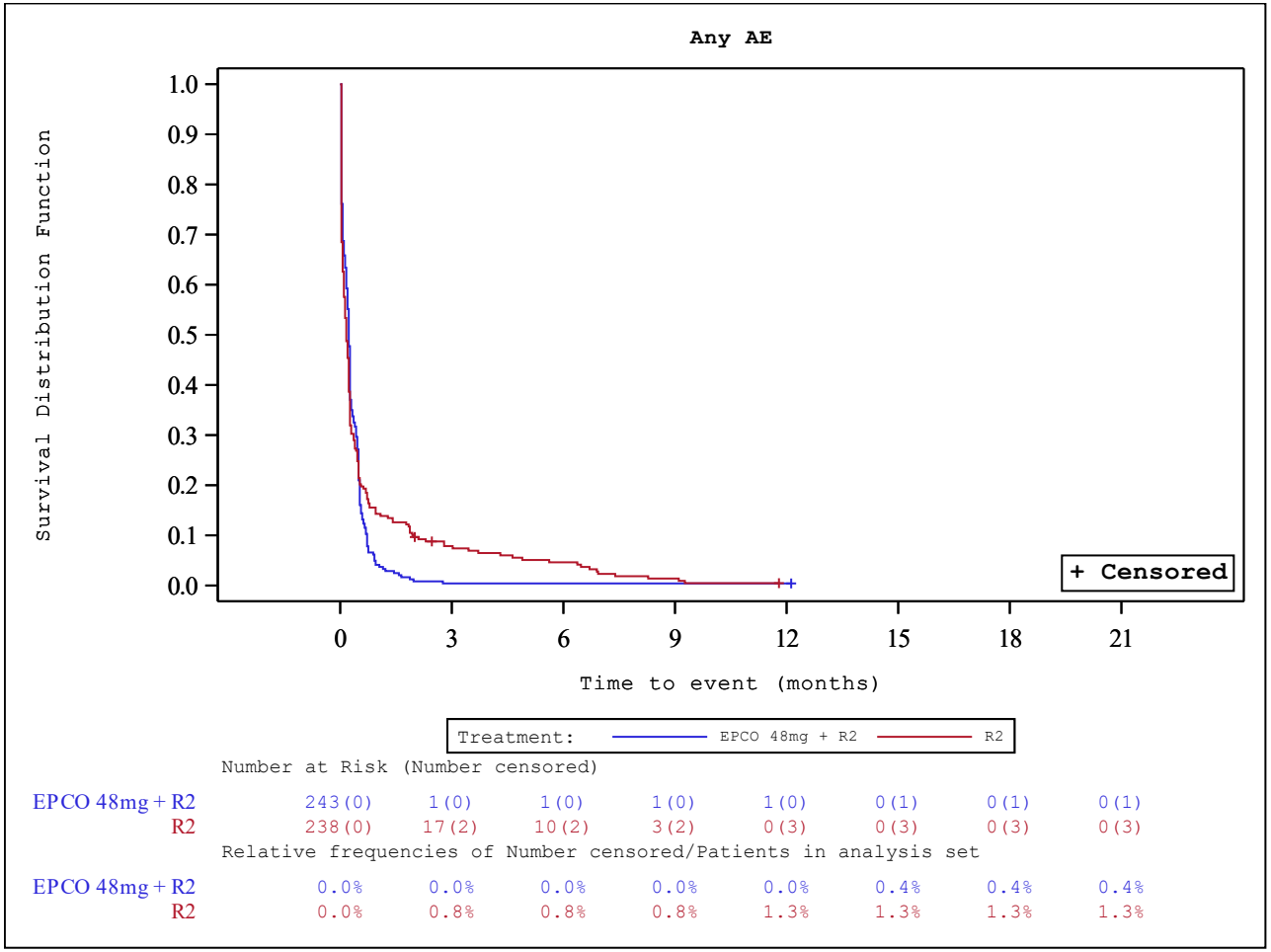
Effect measures are calculated if each subgroup level comprises at least 10 patients.
Analysis displays End of Treatment estimates from MMRM.
Mixed-Effect Model with Repeated Measures (MMRM) analysis with treatment arm as fixed factor and baseline score as covariate and at least one non-missing post-baseline score along with time and treatment-by-time interaction with unstructured covariance structure are included in the model.
Mean differences and Hedges`g < 0 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
n* describes Number of unique subjects contributing to the model estimates, e.g. all patients with observed measurements at both baseline and at least one post-baseline visit.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL=Baseline, N=Number of subjects in Intention-to-Treat Analysis Set, n=number of patients with non-missing value at baseline, SD=Standard Deviation, LSMean=Least Square Mean, SE=Standard Error; CI=Confidence Interval

Table 4.1.1 Time to first Adverse Event

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	242/243 (99.6)	235/238 (98.7)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	0.07 (0.03, 0.07)	0.03 (NE , NE)
Median (95% CI)	0.23 (0.20, 0.26)	0.16 (0.13, 0.23)
75%-ile (95% CI)	0.49 (0.43, 0.53)	0.46 (0.30, 0.62)
Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	1.13 (0.93, 1.35)	
p-value	0.1749	
Relative Risk (95% CI)	1.01 (0.99, 1.03)	
p-value	0.3084	
Odds Ratio (95% CI)	3.09 (0.32, 29.91)	
p-value	0.3302	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3073	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.1 Kaplan-Meier Plot of Time to first Adverse Event



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.1.S Time to first Adverse Event - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.3887
<65	154/ 155 (99.4)	0.23 (0.20, 0.26)	134/ 137 (97.8)	0.20 (0.13, 0.23)	1.18 (0.93, 1.50)	0.1457	
>=65	88/ 88 (100.0)	0.26 (0.16, 0.33)	101/ 101 (100.0)	0.16 (0.07, 0.23)	1.06 (0.79, 1.43)	0.6701	
Sex							0.0545
Male	138/ 139 (99.3)	0.26 (0.20, 0.26)	133/ 135 (98.5)	0.16 (0.10, 0.20)	0.99 (0.78, 1.26)	0.9179	
Female	104/ 104 (100.0)	0.23 (0.16, 0.26)	102/ 103 (99.0)	0.23 (0.10, 0.26)	1.33 (1.00, 1.78)	0.0346	
Disease Status 2L							0.1656
2L: progression of disease <= 2 years	62/ 63 (98.4)	0.26 (0.13, 0.36)	59/ 61 (96.7)	0.26 (0.16, 0.36)	1.31 (0.91, 1.89)	0.1205	
2L: progression of disease > 2 years	94/ 94 (100.0)	0.26 (0.20, 0.33)	93/ 94 (98.9)	0.07 (0.03, 0.16)	0.89 (0.66, 1.19)	0.3736	
Disease Status 3L+							0.9529
3L+: < 6 months	23/ 23 (100.0)	0.20 (0.10, 0.26)	22/ 22 (100.0)	0.20 (0.03, 0.36)	1.39 (0.74, 2.62)	0.2679	
3L+: >= 6 months	63/ 63 (100.0)	0.23 (0.10, 0.26)	61/ 61 (100.0)	0.16 (0.10, 0.23)	1.26 (0.87, 1.83)	0.1763	
Region							0.0662
US/Western Europe	58/ 58 (100.0)	0.20 (0.13, 0.26)	57/ 57 (100.0)	0.07 (0.03, 0.16)	0.83 (0.58, 1.21)	0.2725	
Rest of world	184/ 185 (99.5)	0.23 (0.20, 0.26)	178/ 181 (98.3)	0.20 (0.16, 0.23)	1.20 (0.97, 1.49)	0.0719	
Number of prior anti-lymphoma therapies							0.2714
2L	156/ 157 (99.4)	0.26 (0.20, 0.30)	152/ 155 (98.1)	0.16 (0.10, 0.23)	1.05 (0.83, 1.32)	0.6712	
3L+	86/ 86 (100.0)	0.21 (0.13, 0.26)	83/ 83 (100.0)	0.16 (0.10, 0.23)	1.29 (0.93, 1.77)	0.0922	

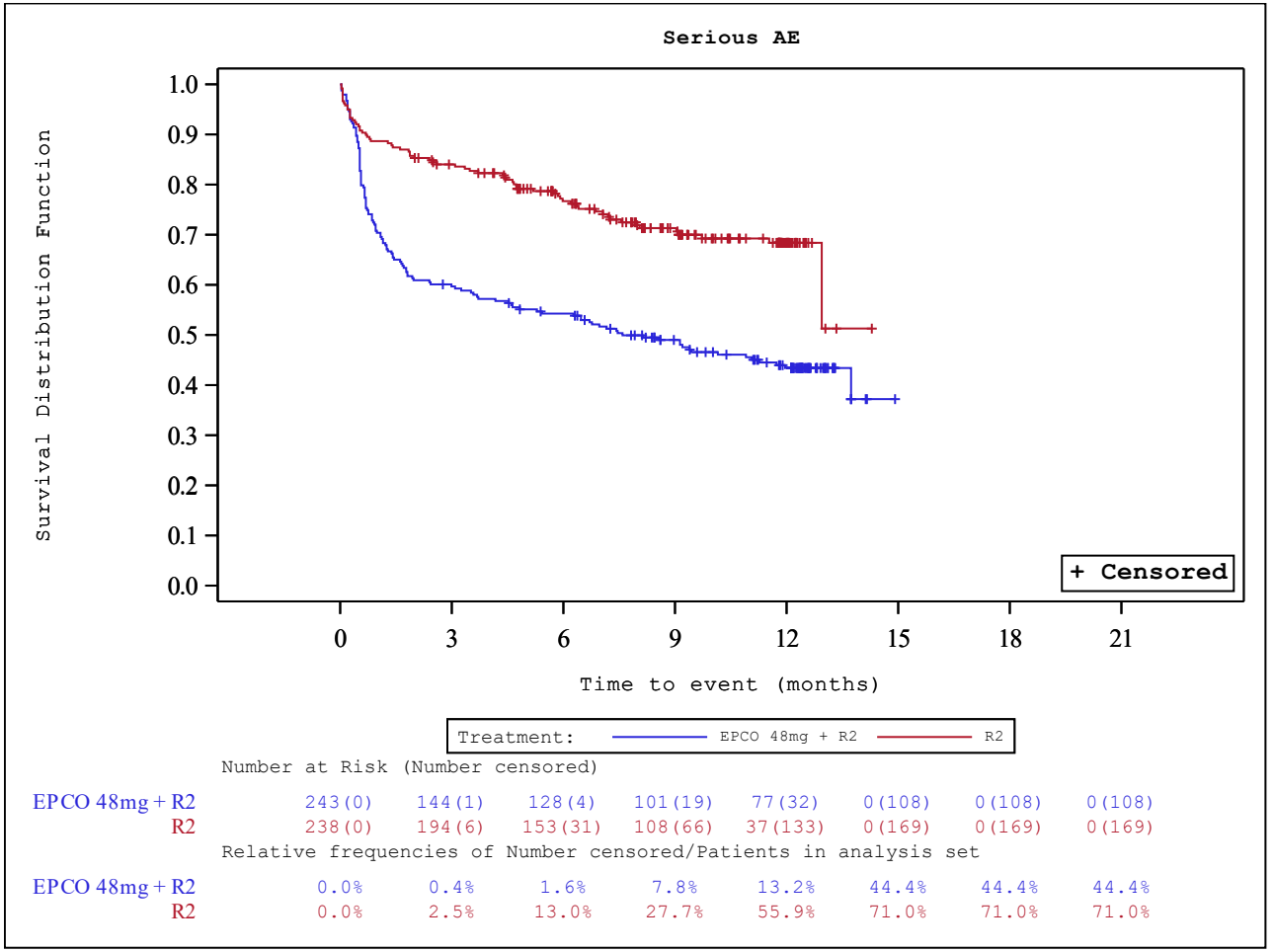
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.2 Time to first Serious Adverse Event

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	135/243 (55.6)	69/238 (29.0)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	0.72 (0.56, 1.08)	6.87 (4.63, 11.53)
Median (95% CI)	7.59 (4.53, 11.96)	NE (12.94, NE)
75%-ile (95% CI)	NE (13.73, NE)	NE (12.94, NE)
Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	2.19 (1.64, 2.93)	
p-value	<.0001	
Relative Risk (95% CI)	1.92 (1.52, 2.41)	
p-value	<.0001	
Odds Ratio (95% CI)	3.06 (2.10, 4.47)	
p-value	<.0001	
Risk Difference (95% CI)	0.27 (0.18, 0.35)	
p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.2 Kaplan-Meier Plot of Time to first Serious Adverse Event



Number at Risk (Number censored)

EPCO 48mg + R2	243(0)	144(1)	128(4)	101(19)	77(32)	0(108)	0(108)	0(108)
R2	238(0)	194(6)	153(31)	108(66)	37(133)	0(169)	0(169)	0(169)

Relative frequencies of Number censored/Patients in analysis set

EPCO 48mg + R2	0.0%	0.4%	1.6%	7.8%	13.2%	44.4%	44.4%	44.4%
R2	0.0%	2.5%	13.0%	27.7%	55.9%	71.0%	71.0%	71.0%

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.2.S Time to first Serious Adverse Event - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.2194
<65	82/ 155 (52.9)	9.40 (4.17, NE)	32/ 137 (23.4)	12.94 (NE , NE)	2.62 (1.74, 3.95)	<.0001	
>=65	53/ 88 (60.2)	6.47 (1.81, 11.07)	37/ 101 (36.6)	NE (9.10, NE)	1.87 (1.23, 2.84)	0.0030	
Sex							0.8965
Male	74/ 139 (53.2)	9.40 (6.28, NE)	36/ 135 (26.7)	NE (NE , NE)	2.15 (1.44, 3.21)	0.0001	
Female	61/ 104 (58.7)	4.60 (1.81, 11.73)	33/ 103 (32.0)	12.94 (12.94, NE)	2.25 (1.47, 3.44)	0.0001	
Disease Status 2L							0.1748
2L: progression of disease <= 2 years	30/ 63 (47.6)	NE (3.09, NE)	19/ 61 (31.1)	NE (9.03, NE)	1.54 (0.87, 2.75)	0.1364	
2L: progression of disease > 2 years	51/ 94 (54.3)	6.47 (1.81, NE)	23/ 94 (24.5)	NE (NE , NE)	2.68 (1.64, 4.39)	<.0001	
Disease Status 3L+							0.3306
3L+: < 6 months	17/ 23 (73.9)	2.40 (0.53, 9.20)	6/ 22 (27.3)	NE (7.20, NE)	3.41 (1.33, 8.76)	0.0063	
3L+: >= 6 months	37/ 63 (58.7)	7.59 (4.17, NE)	21/ 61 (34.4)	12.94 (12.94, NE)	2.04 (1.18, 3.52)	0.0087	
Region							0.2614
US/Western Europe	34/ 58 (58.6)	4.16 (1.15, NE)	22/ 57 (38.6)	NE (5.98, NE)	1.70 (0.99, 2.91)	0.0494	
Rest of world	101/ 185 (54.6)	9.13 (4.83, NE)	47/ 181 (26.0)	NE (12.94, NE)	2.42 (1.71, 3.43)	<.0001	
Number of prior anti-lymphoma therapies							0.8357
2L	81/ 157 (51.6)	10.91 (3.58, NE)	42/ 155 (27.1)	NE (NE , NE)	2.16 (1.49, 3.14)	<.0001	
3L+	54/ 86 (62.8)	6.77 (1.94, 9.20)	27/ 83 (32.5)	12.94 (12.94, NE)	2.31 (1.45, 3.67)	0.0003	

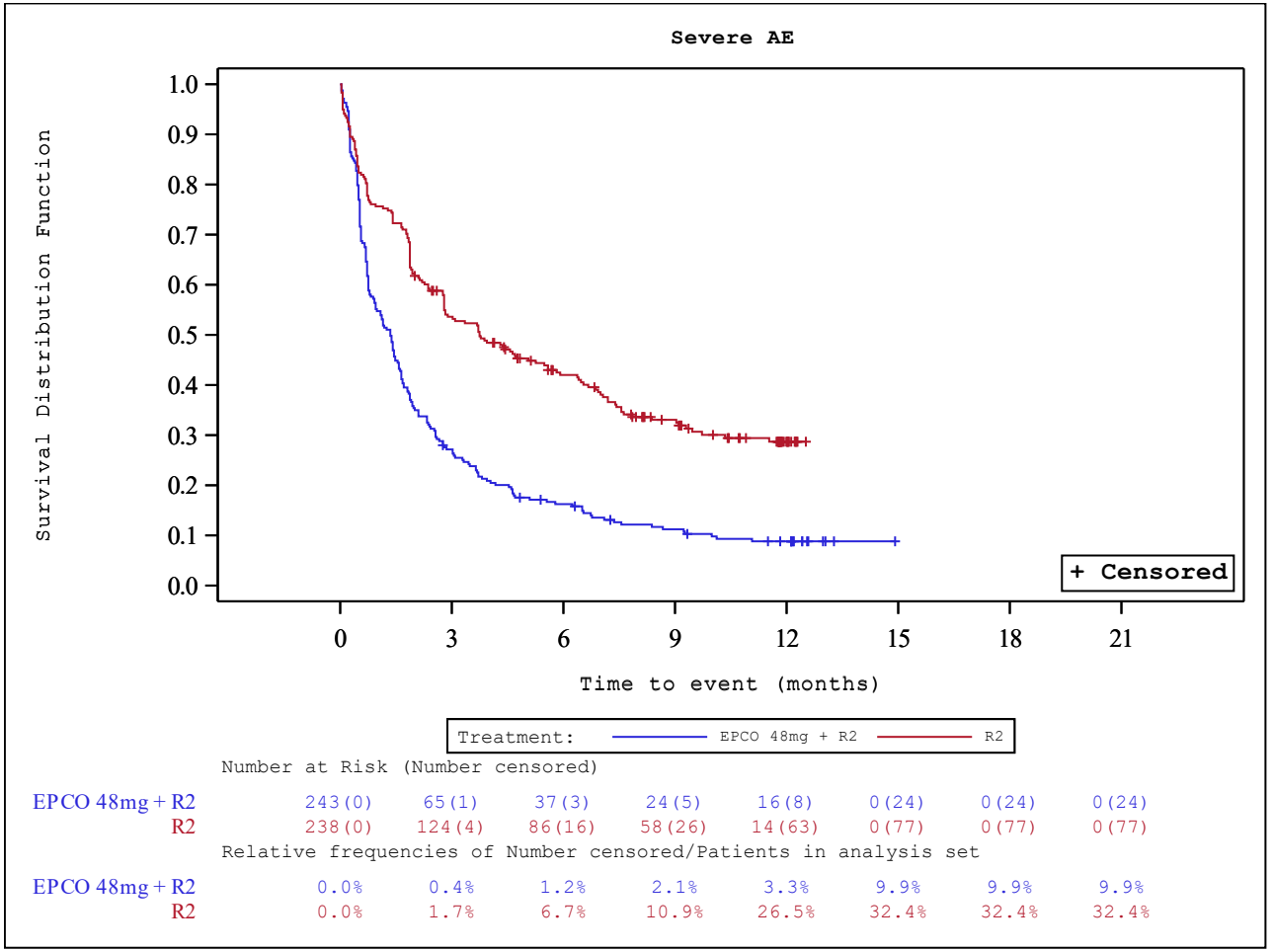
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.3 Time to first Severe Adverse Event

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	219/243 (90.1)	161/238 (67.6)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	0.53 (0.46, 0.56)	1.28 (0.69, 1.81)
Median (95% CI)	1.35 (0.92, 1.58)	3.75 (2.79, 5.59)
75%-ile (95% CI)	3.32 (2.56, 4.53)	NE (9.46, NE)
Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	2.04 (1.66, 2.51)	
p-value	<.0001	
Relative Risk (95% CI)	1.33 (1.21, 1.47)	
p-value	<.0001	
Odds Ratio (95% CI)	4.36 (2.64, 7.20)	
p-value	<.0001	
Risk Difference (95% CI)	0.22 (0.15, 0.30)	
p-value	<.0001	

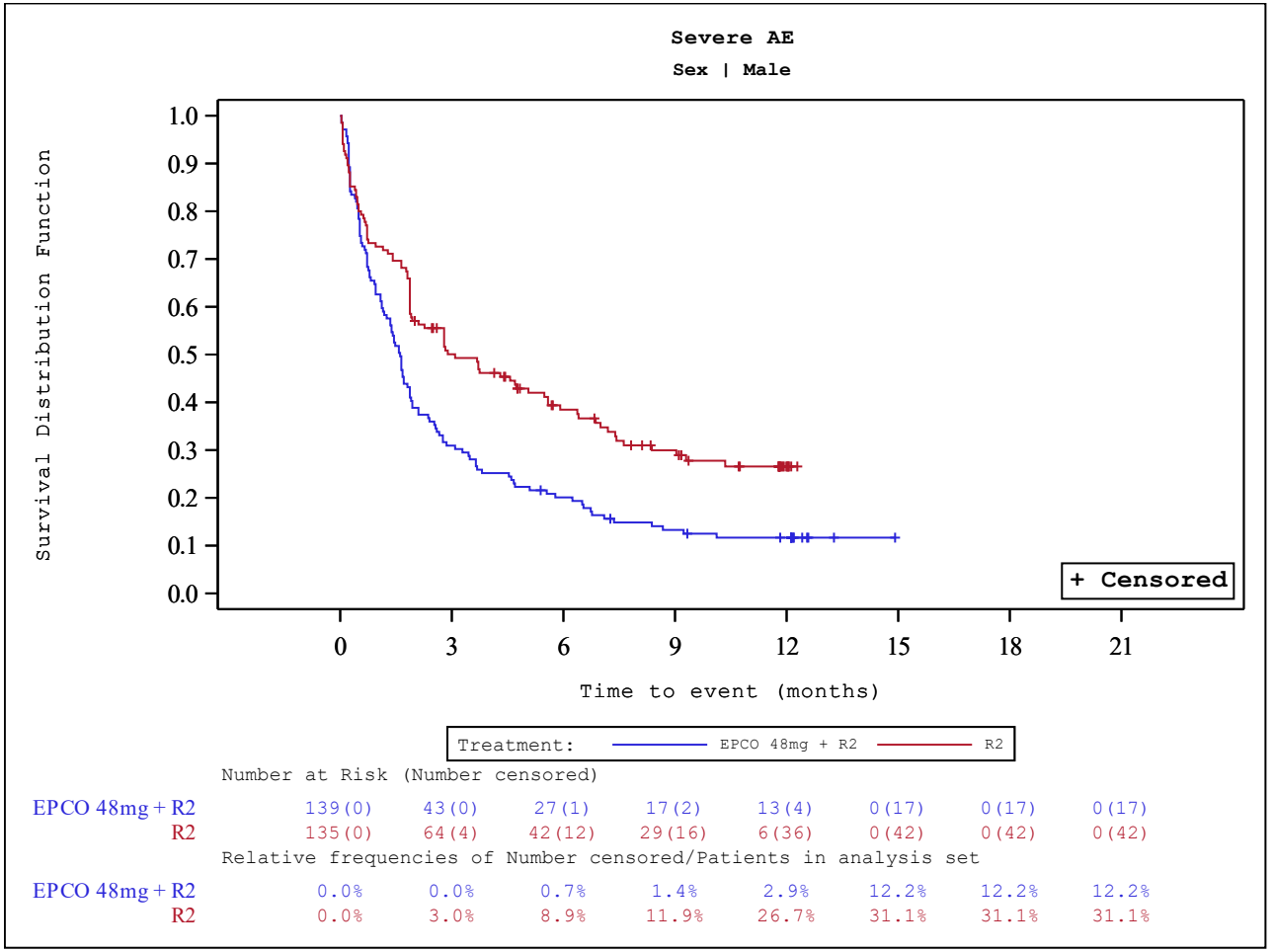
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.3 Kaplan-Meier Plot of Time to first Severe Adverse Event



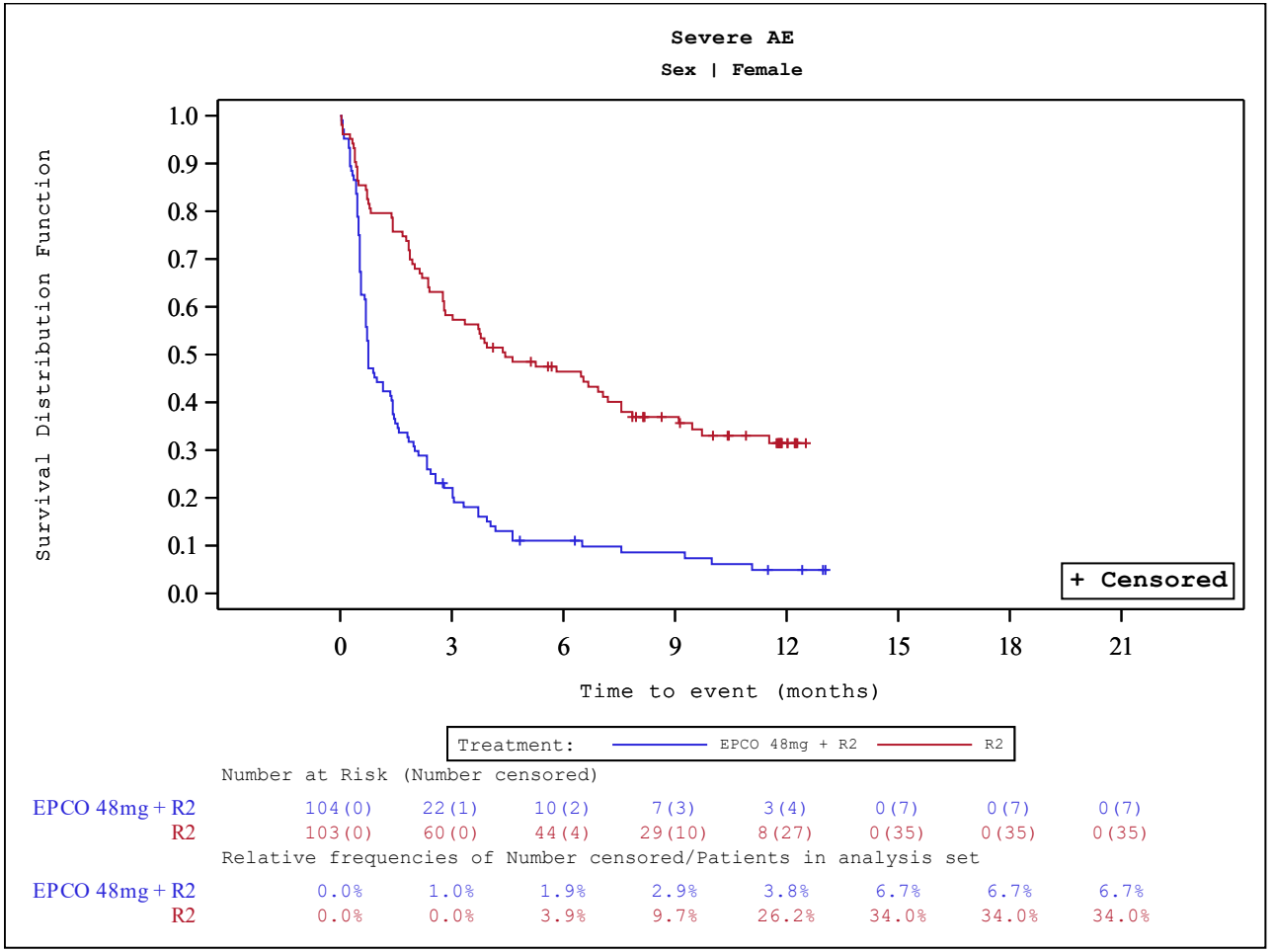
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.3 Kaplan-Meier Plot of Time to first Severe Adverse Event



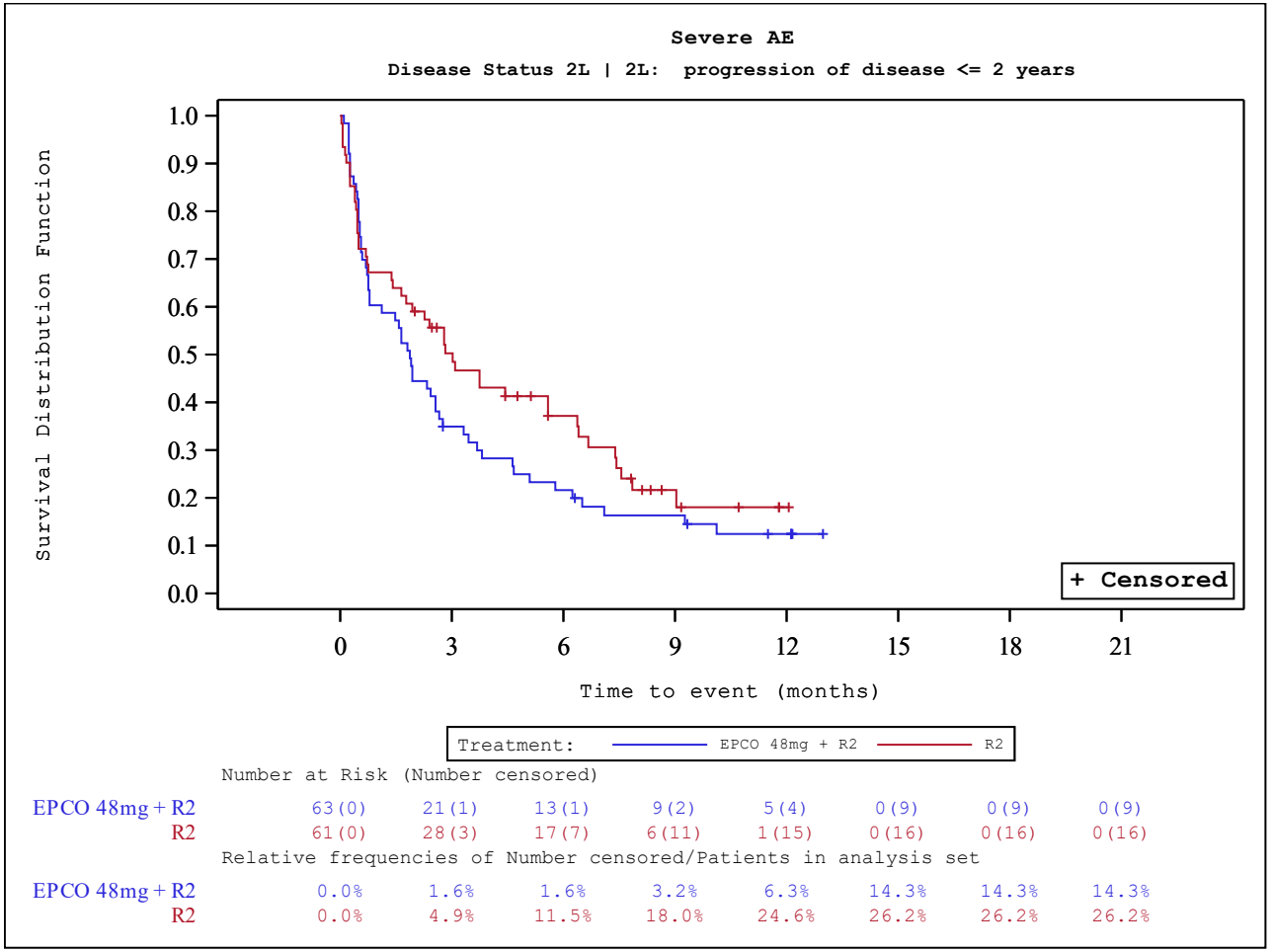
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.3 Kaplan-Meier Plot of Time to first Severe Adverse Event

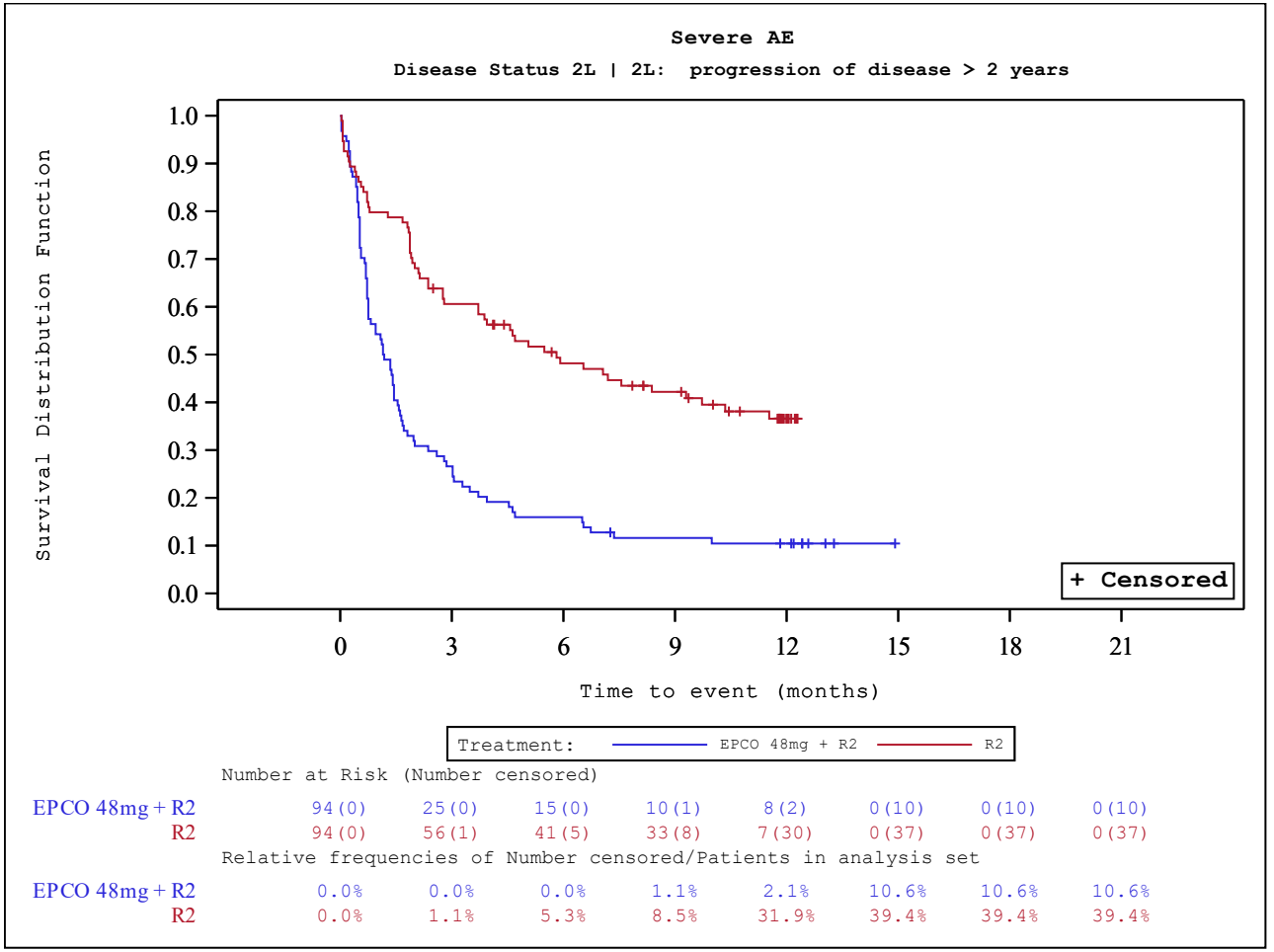


Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.3 Kaplan-Meier Plot of Time to first Severe Adverse Event

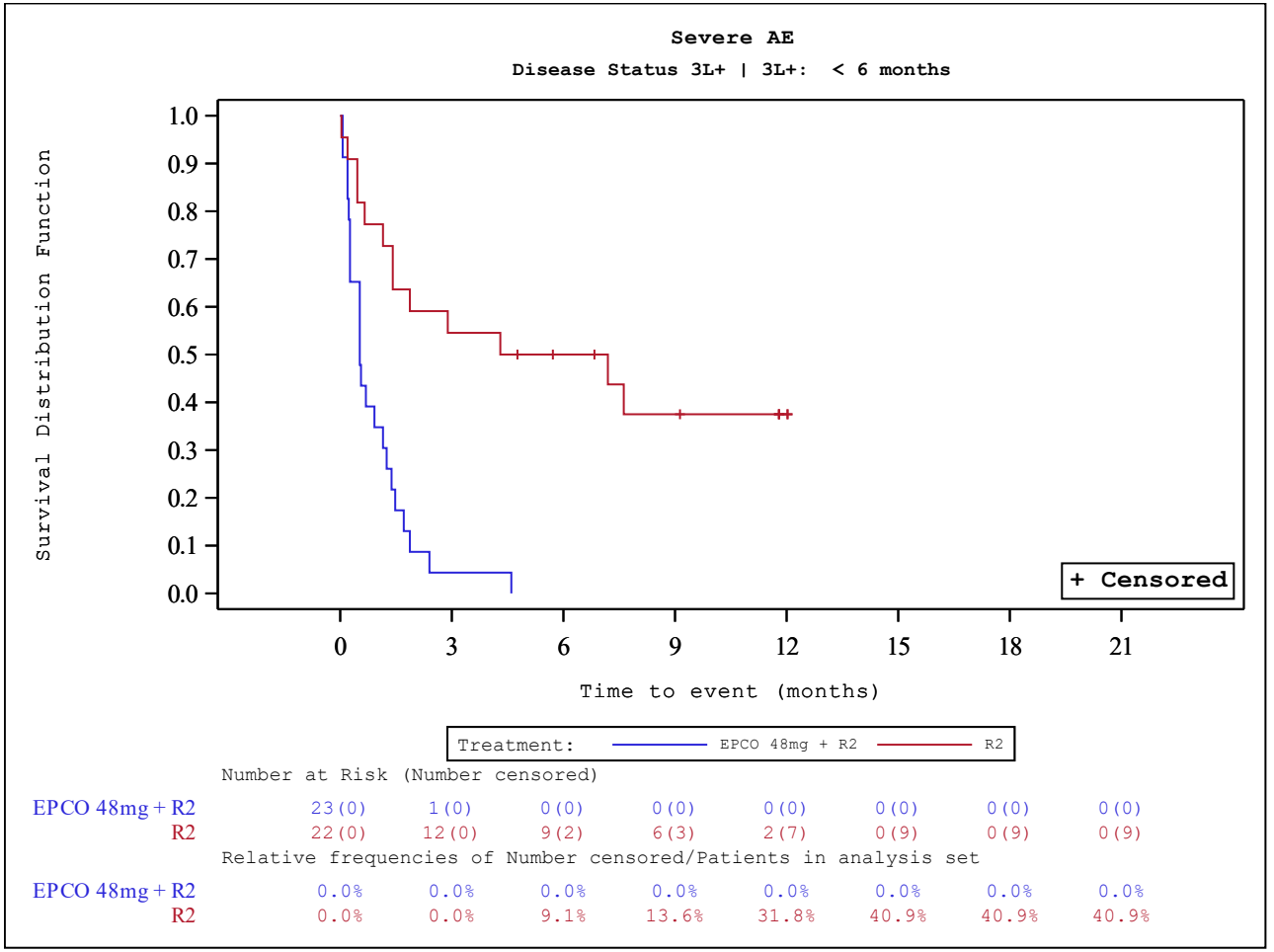


Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.



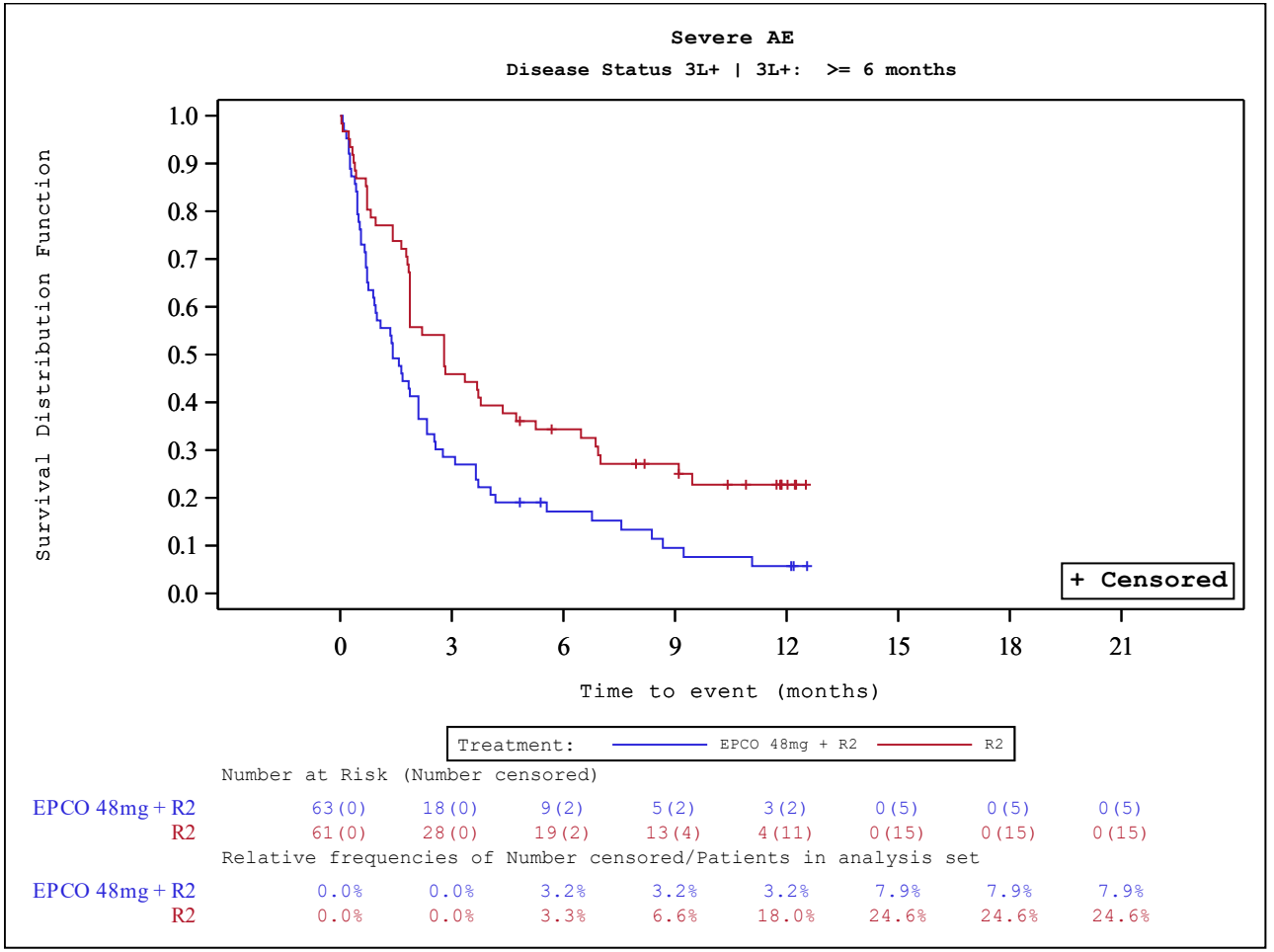
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.3 Kaplan-Meier Plot of Time to first Severe Adverse Event



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.3 Kaplan-Meier Plot of Time to first Severe Adverse Event



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.3.S Time to first Severe Adverse Event - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.1912
<65	136/ 155 (87.7)	1.25 (0.76, 1.64)	82/ 137 (59.9)	5.59 (3.68, 7.62)	2.27 (1.72, 3.00)	<.0001	
>=65	83/ 88 (94.3)	1.40 (0.82, 1.64)	79/ 101 (78.2)	2.27 (1.87, 4.30)	1.85 (1.35, 2.54)	<.0001	
Sex							0.0165
Male	122/ 139 (87.8)	1.61 (1.18, 1.87)	93/ 135 (68.9)	3.09 (1.87, 5.49)	1.65 (1.26, 2.17)	0.0002	
Female	97/ 104 (93.3)	0.76 (0.69, 1.38)	68/ 103 (66.0)	4.44 (2.79, 7.20)	2.77 (2.01, 3.82)	<.0001	
Disease Status 2L							0.0132
2L: progression of disease <= 2 years	54/ 63 (85.7)	1.87 (0.79, 2.56)	45/ 61 (73.8)	3.02 (1.64, 5.59)	1.31 (0.88, 1.94)	0.1842	
2L: progression of disease > 2 years	84/ 94 (89.4)	1.17 (0.76, 1.54)	57/ 94 (60.6)	5.82 (2.79, 9.72)	2.53 (1.79, 3.56)	<.0001	
Disease Status 3L+							0.0041
3L+: < 6 months	23/ 23 (100.0)	0.53 (0.26, 1.15)	13/ 22 (59.1)	5.75 (1.15, NE)	4.54 (2.10, 9.78)	<.0001	
3L+: >= 6 months	58/ 63 (92.1)	1.41 (0.89, 2.10)	46/ 61 (75.4)	2.79 (1.87, 4.37)	1.78 (1.21, 2.63)	0.0030	
Region							0.0709
US/Western Europe	47/ 58 (81.0)	1.66 (0.79, 3.65)	38/ 57 (66.7)	2.20 (1.77, 7.39)	1.44 (0.93, 2.20)	0.0947	
Rest of world	172/ 185 (93.0)	1.18 (0.76, 1.48)	123/ 181 (68.0)	3.88 (2.79, 5.82)	2.34 (1.84, 2.96)	<.0001	
Number of prior anti-lymphoma therapies							0.6164
2L	138/ 157 (87.9)	1.41 (0.82, 1.68)	102/ 155 (65.8)	4.57 (2.79, 6.54)	1.95 (1.51, 2.53)	<.0001	
3L+	81/ 86 (94.2)	1.12 (0.69, 1.58)	59/ 83 (71.1)	2.83 (1.87, 5.26)	2.24 (1.59, 3.15)	<.0001	

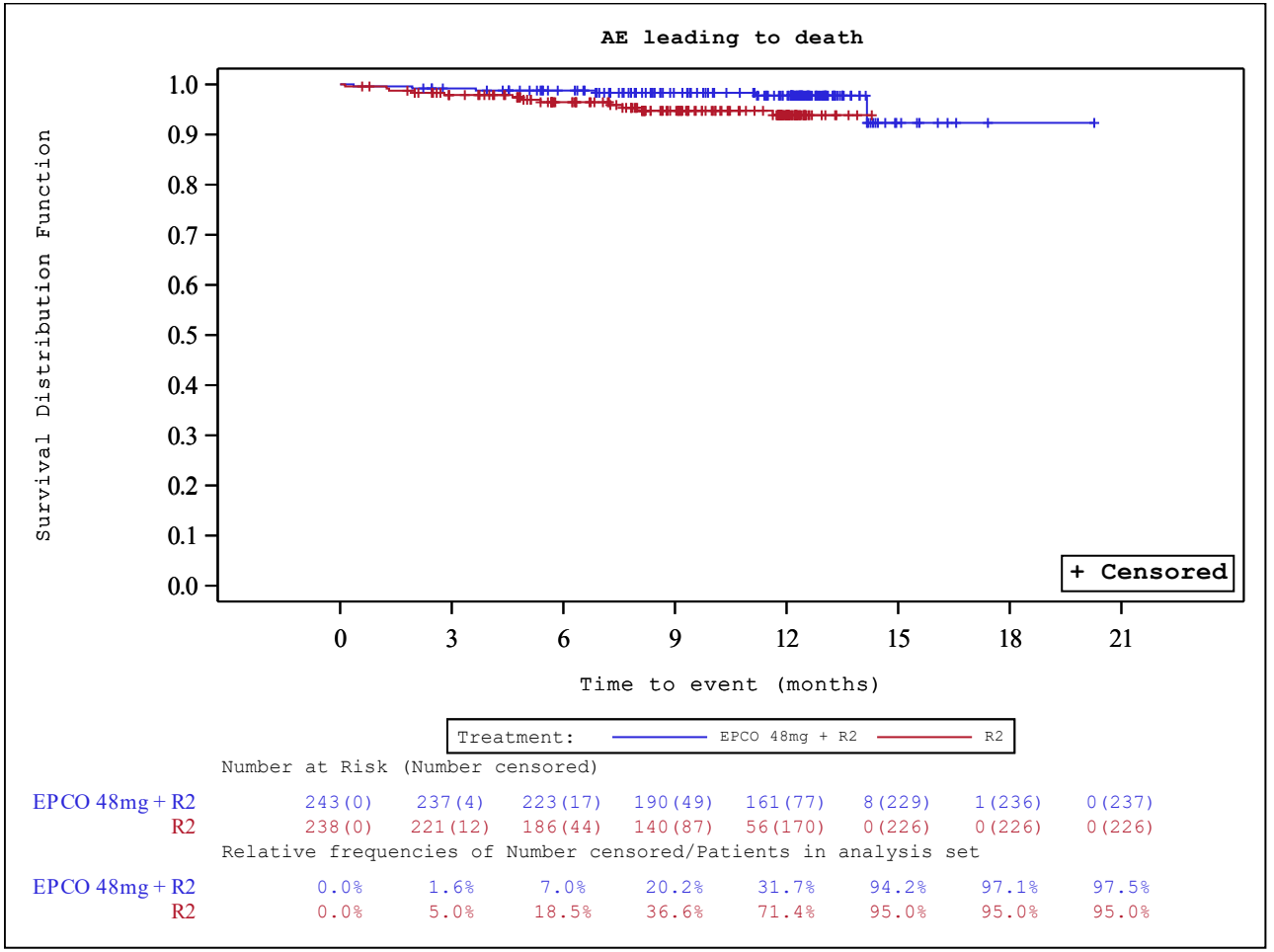
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.4 Time to first Adverse Event leading to Death

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	6/243 (2.5)	12/238 (5.0)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	NE (14.16, NE)	NE (NE , NE)
Median (95% CI)	NE (NE , NE)	NE (NE , NE)
75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.37 (0.13, 1.04)	
p-value	0.0501	
Relative Risk (95% CI)	0.49 (0.19, 1.28)	
p-value	0.1464	
Odds Ratio (95% CI)	0.48 (0.18, 1.29)	
p-value	0.1453	
Risk Difference (95% CI)	-0.03 (-0.06, 0.01)	
p-value	0.1376	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.4 Kaplan-Meier Plot of Time to first Adverse Event leading to Death



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.4.S Time to first Adverse Event leading to Death - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.3494
<65	2/ 155 (1.3)	NE (NE , NE)	6/ 137 (4.4)	NE (NE , NE)	0.13 (0.02, 1.07)	0.0249	
>=65	4/ 88 (4.5)	NE (NE , NE)	6/ 101 (5.9)	NE (NE , NE)	0.68 (0.19, 2.42)	0.5520	
Sex							
Male	4/ 139 (2.9)	NE (NE , NE)	5/ 135 (3.7)	NE (NE , NE)			
Female	2/ 104 (1.9)	NE (14.16, NE)	7/ 103 (6.8)	NE (NE , NE)			
Disease Status 2L							
2L: progression of disease <= 2 years	1/ 63 (1.6)	NE (14.16, NE)	4/ 61 (6.6)	NE (NE , NE)			
2L: progression of disease > 2 years	3/ 94 (3.2)	NE (NE , NE)	6/ 94 (6.4)	NE (NE , NE)			
Disease Status 3L+							
3L+: < 6 months	2/ 23 (8.7)	NE (NE , NE)	2/ 22 (9.1)	NE (NE , NE)			
3L+: >= 6 months	0/ 63 (0.0)	NE (NE , NE)	0/ 61 (0.0)	NE (NE , NE)			
Region							0.9915
US/Western Europe	0/ 58 (0.0)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	NE		
Rest of world	6/ 185 (3.2)	NE (NE , NE)	11/ 181 (6.1)	NE (NE , NE)	0.41 (0.15, 1.15)	0.0813	
Number of prior anti-lymphoma therapies							0.3942
2L	4/ 157 (2.5)	NE (NE , NE)	10/ 155 (6.5)	NE (NE , NE)	0.25 (0.07, 0.90)	0.0223	
3L+	2/ 86 (2.3)	NE (NE , NE)	2/ 83 (2.4)	NE (NE , NE)	0.95 (0.13, 6.76)	0.9612	

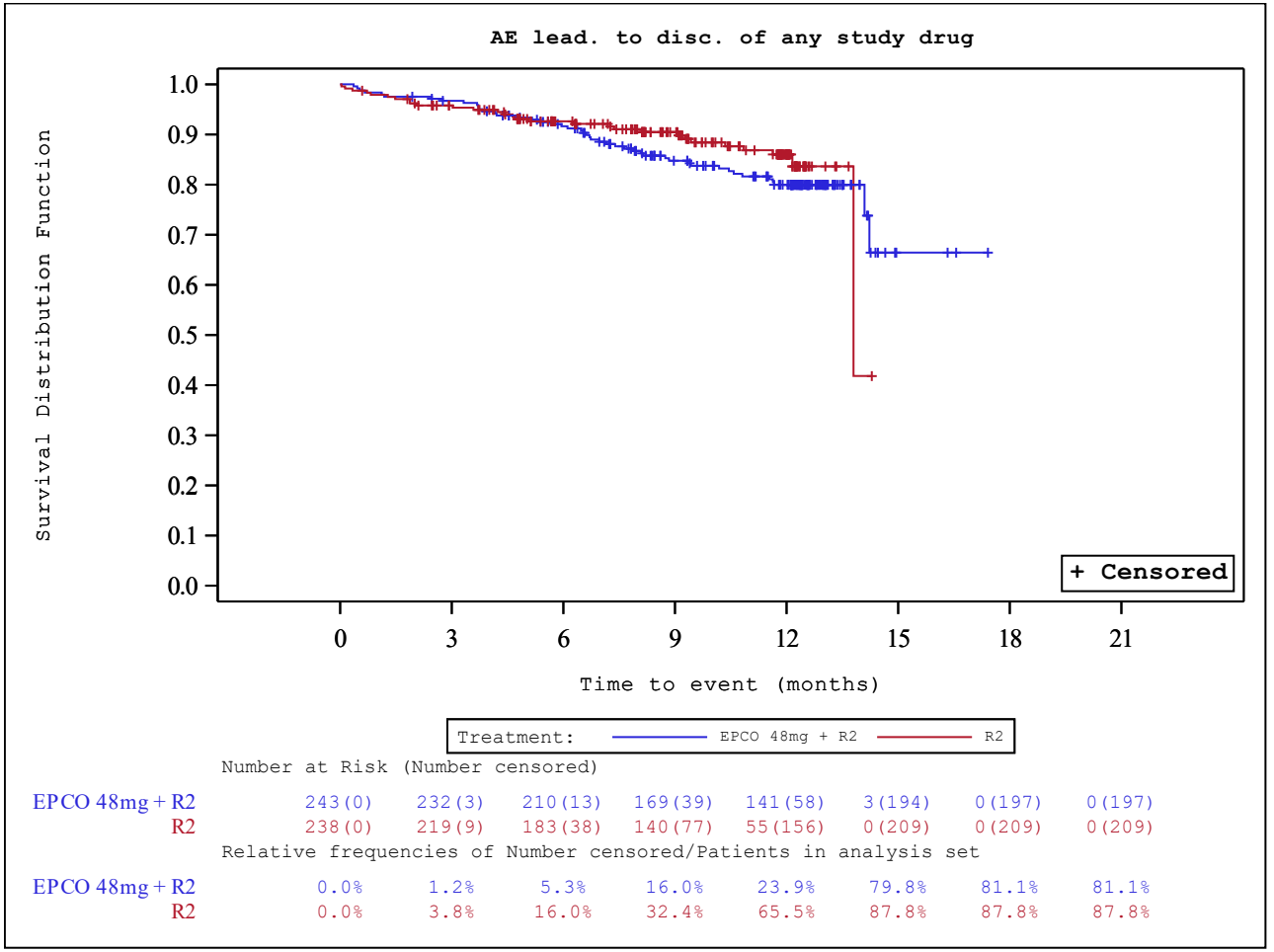
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.5 Time to first Adverse Event leading to Discontinuation of any Study Drug

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	46/243 (18.9)	29/238 (12.2)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	14.09 (11.63, NE)	13.80 (13.80, NE)
Median (95% CI)	NE (14.23, NE)	13.80 (13.80, NE)
75%-ile (95% CI)	NE (NE , NE)	NE (13.80, NE)
Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	1.30 (0.81, 2.08)	
p-value	0.2701	
Relative Risk (95% CI)	1.55 (1.01, 2.39)	
p-value	0.0441	
Odds Ratio (95% CI)	1.68 (1.02, 2.79)	
p-value	0.0429	
Risk Difference (95% CI)	0.07 (0.00, 0.13)	
p-value	0.0402	

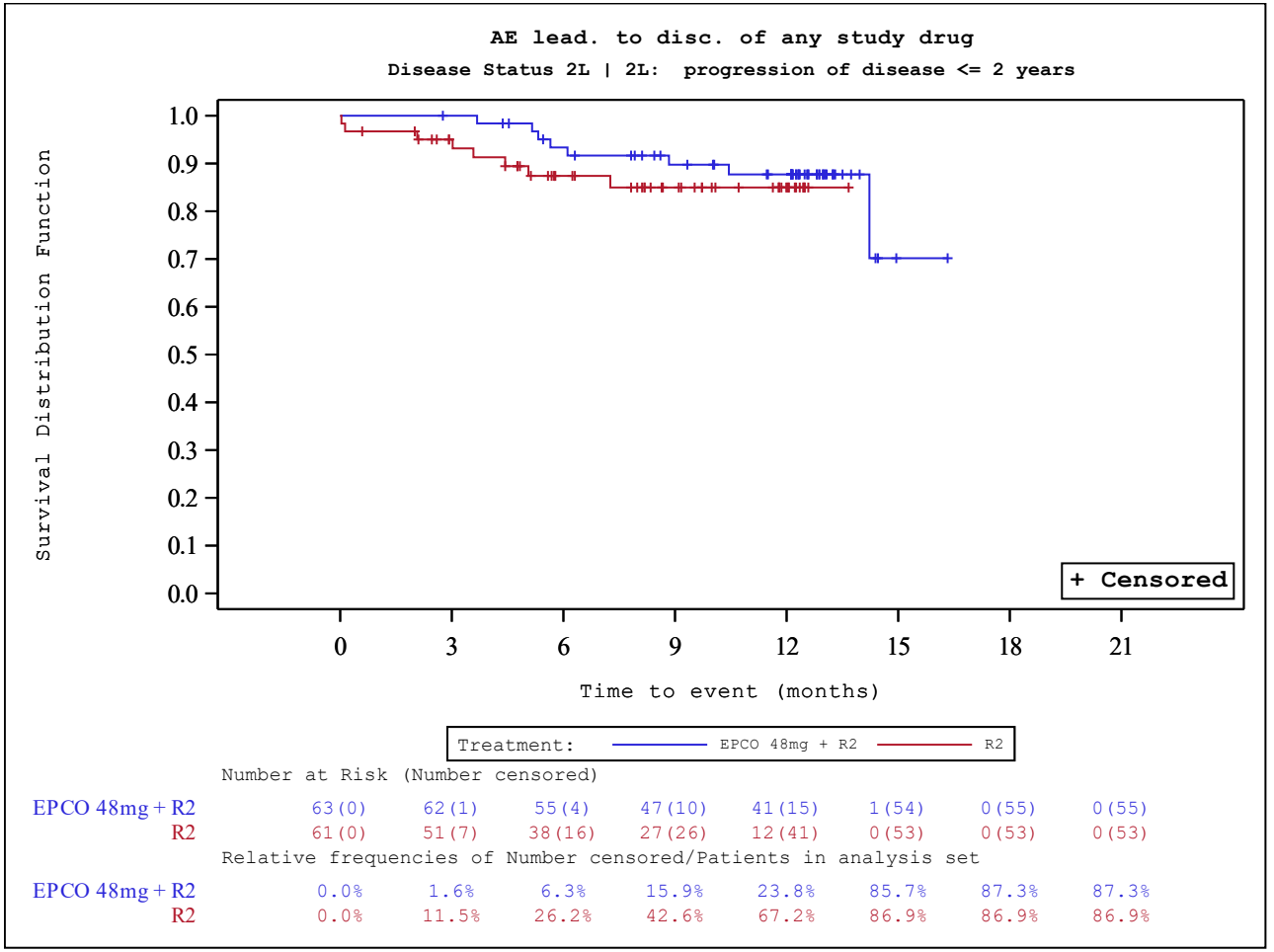
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Figure 4.1.5 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of any Study Drug



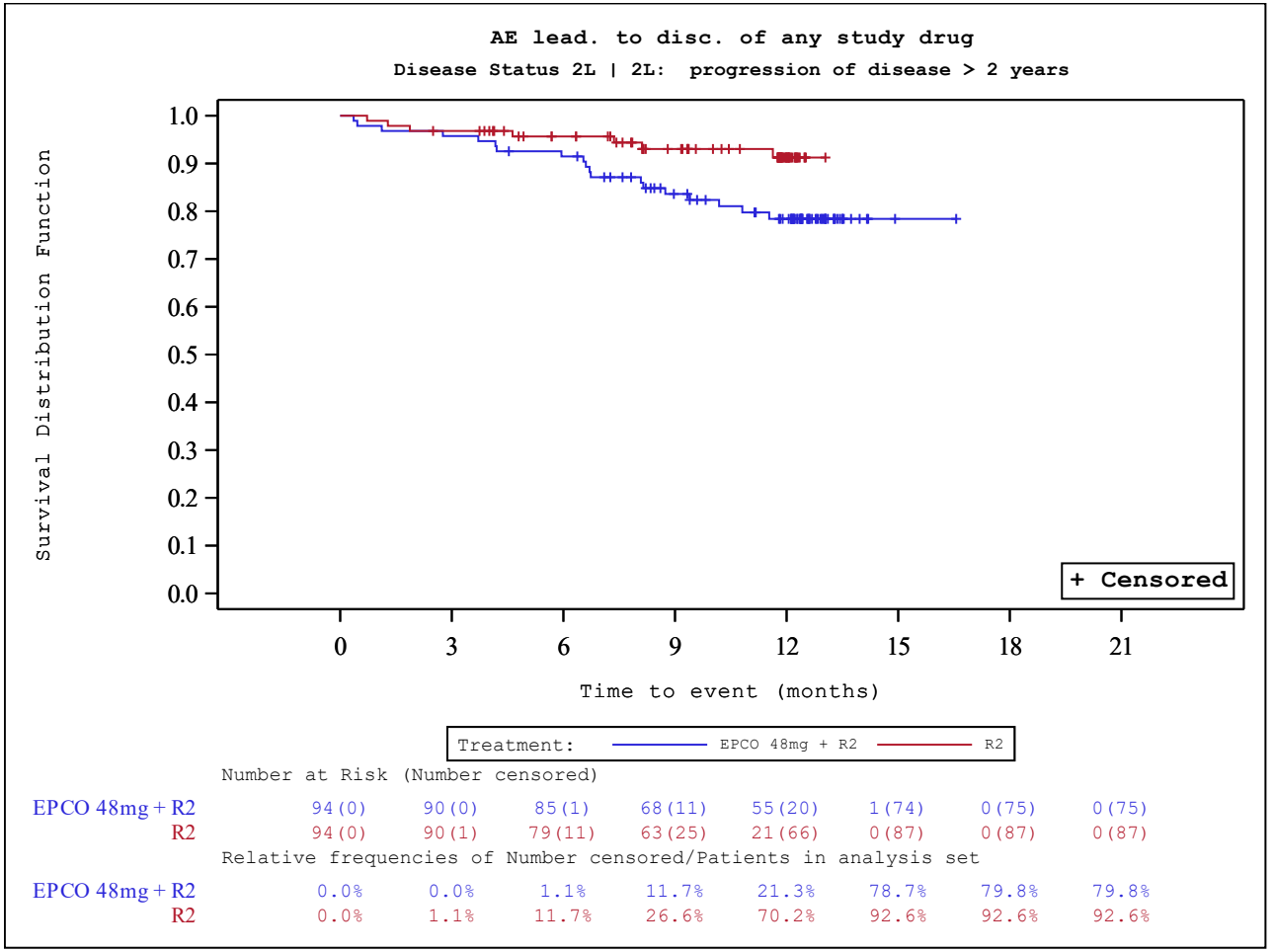
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.5 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of any Study Drug



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.5 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of any Study Drug



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.5.S Time to first Adverse Event leading to Discontinuation of any Study Drug - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							0.9846
<65	24/ 155 (15.5)	NE (14.09, NE)	13/ 137 (9.5)	13.80 (NE , NE)	1.28 (0.64, 2.55)	0.4876	
>=65	22/ 88 (25.0)	NE (NE , NE)	16/ 101 (15.8)	NE (NE , NE)	1.42 (0.74, 2.70)	0.2893	
Sex							0.9634
Male	23/ 139 (16.5)	NE (NE , NE)	13/ 135 (9.6)	NE (NE , NE)	1.45 (0.73, 2.87)	0.2832	
Female	23/ 104 (22.1)	14.23 (14.09, NE)	16/ 103 (15.5)	13.80 (13.80, NE)	1.26 (0.66, 2.40)	0.4802	
Disease Status 2L							0.0474
2L: progression of disease <= 2 years	8/ 63 (12.7)	NE (14.23, NE)	8/ 61 (13.1)	NE (NE , NE)	0.65 (0.24, 1.80)	0.4061	
2L: progression of disease > 2 years	19/ 94 (20.2)	NE (NE , NE)	7/ 94 (7.4)	NE (NE , NE)	2.57 (1.08, 6.10)	0.0271	
Disease Status 3L+							0.8163
3L+: < 6 months	5/ 23 (21.7)	NE (7.92, NE)	3/ 22 (13.6)	NE (NE , NE)	1.59 (0.38, 6.66)	0.5217	
3L+: >= 6 months	14/ 63 (22.2)	NE (14.09, NE)	11/ 61 (18.0)	13.80 (13.80, NE)	1.05 (0.48, 2.33)	0.8986	
Region							0.3719
US/Western Europe	12/ 58 (20.7)	NE (NE , NE)	5/ 57 (8.8)	NE (12.16, NE)	2.00 (0.70, 5.69)	0.1872	
Rest of world	34/ 185 (18.4)	NE (14.23, NE)	24/ 181 (13.3)	13.80 (13.80, NE)	1.17 (0.69, 1.99)	0.5615	
Number of prior anti-lymphoma therapies							0.7375
2L	27/ 157 (17.2)	NE (14.23, NE)	15/ 155 (9.7)	NE (NE , NE)	1.49 (0.79, 2.81)	0.2186	
3L+	19/ 86 (22.1)	NE (14.09, NE)	14/ 83 (16.9)	13.80 (13.80, NE)	1.15 (0.57, 2.30)	0.6972	

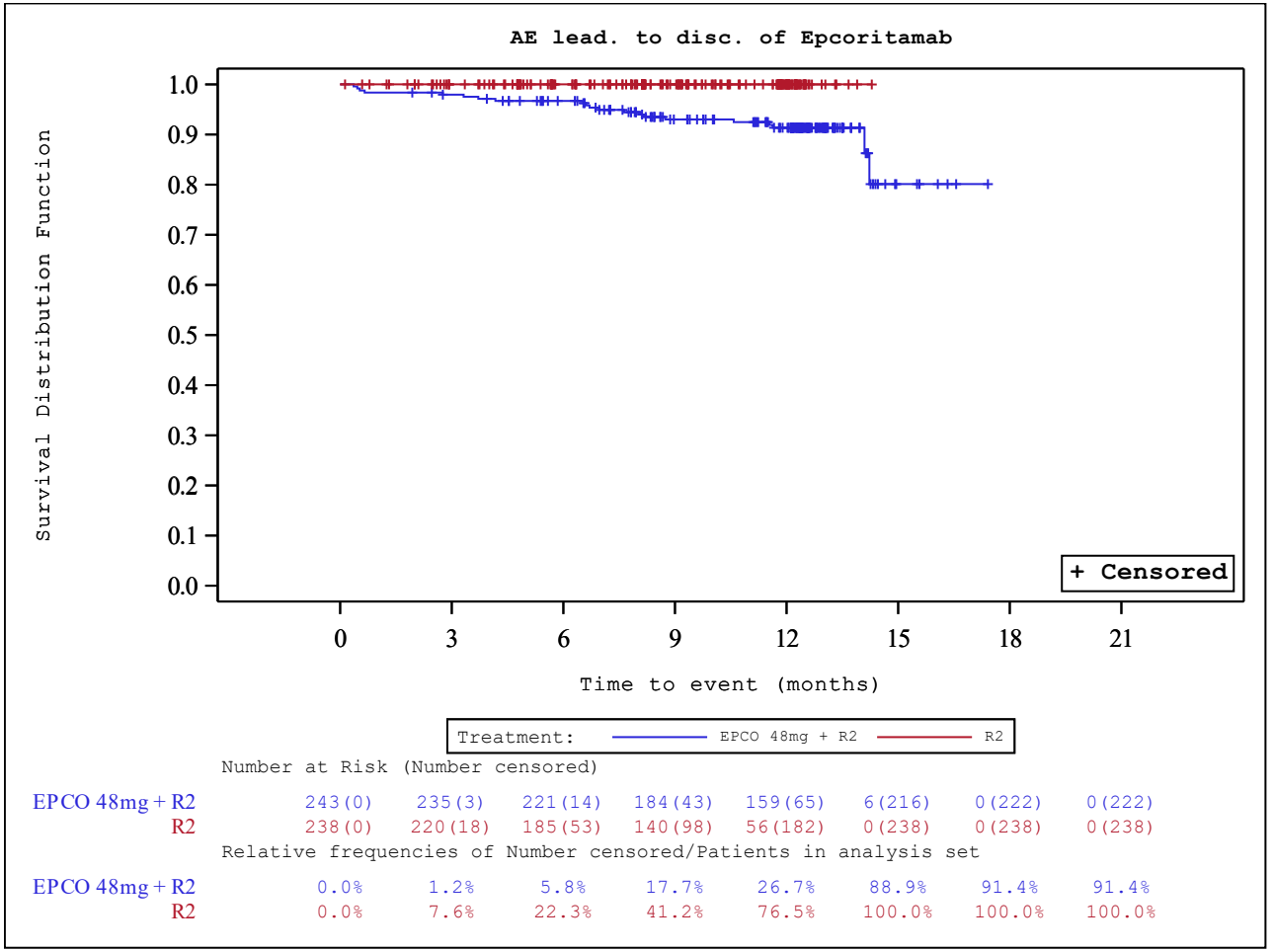
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.6 Time to first Adverse Event leading to Discontinuation of Epcoritamab

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	21/243 (8.6)	0/238 (0.0)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	NE (14.09, NE)	NE (NE , NE)
Median (95% CI)	NE (NE , NE)	NE (NE , NE)
75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	42.12 (2.57, 691.37)	
p-value	0.0088	
Odds Ratio (95% CI)	46.09 (2.78, 765.43)	
p-value	0.0075	
Risk Difference (95% CI)	0.09 (0.05, 0.12)	
p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.6 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of Epcoritamab



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.6.S Time to first Adverse Event leading to Discontinuation of Epcoritamab - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							0.9998
<65	10/ 155 (6.5)	NE (14.23, NE)	0/ 137 (0.0)	NE (NE , NE)	NE		
>=65	11/ 88 (12.5)	NE (NE , NE)	0/ 101 (0.0)	NE (NE , NE)	NE		
Sex							0.9998
Male	8/ 139 (5.8)	NE (NE , NE)	0/ 135 (0.0)	NE (NE , NE)	NE		
Female	13/ 104 (12.5)	NE (14.09, NE)	0/ 103 (0.0)	NE (NE , NE)	NE		
Disease Status 2L							0.9996
2L: progression of disease <= 2 years	1/ 63 (1.6)	NE (14.23, NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
2L: progression of disease > 2 years	12/ 94 (12.8)	NE (NE , NE)	0/ 94 (0.0)	NE (NE , NE)	NE		
Disease Status 3L+							
3L+: < 6 months	2/ 23 (8.7)	NE (NE , NE)	0/ 22 (0.0)	NE (NE , NE)			
3L+: >= 6 months	6/ 63 (9.5)	NE (14.09, NE)	0/ 61 (0.0)	NE (NE , NE)			
Region							0.9999
US/Western Europe	4/ 58 (6.9)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
Rest of world	17/ 185 (9.2)	NE (NE , NE)	0/ 181 (0.0)	NE (NE , NE)	NE		
Number of prior anti-lymphoma therapies							1.0000
2L	13/ 157 (8.3)	NE (NE , NE)	0/ 155 (0.0)	NE (NE , NE)	NE		
3L+	8/ 86 (9.3)	NE (14.09, NE)	0/ 83 (0.0)	NE (NE , NE)	NE		

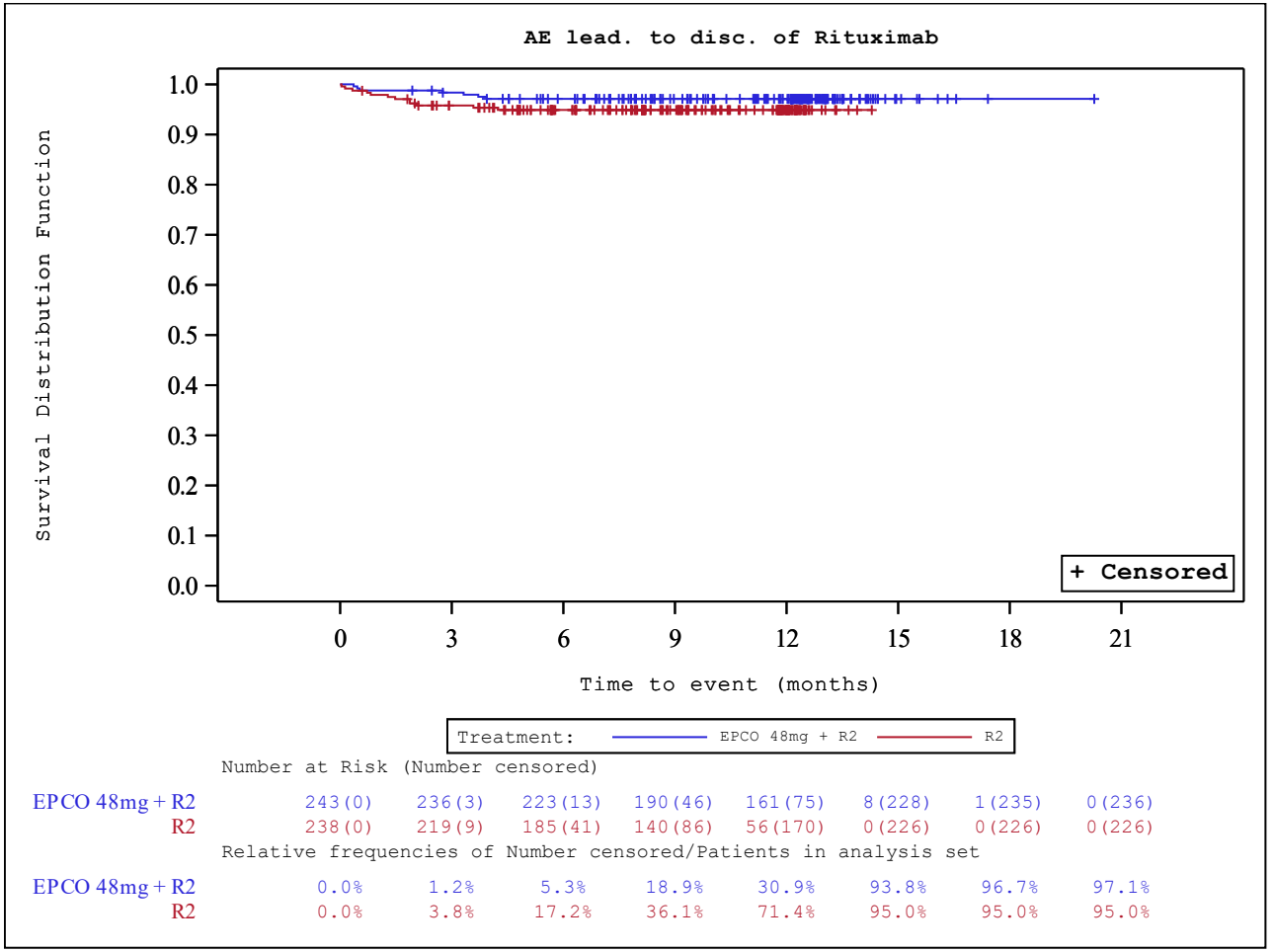
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.1.7 Time to first Adverse Event leading to Discontinuation of Rituximab

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	7/243 (2.9)	12/238 (5.0)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
Median (95% CI)	NE (NE , NE)	NE (NE , NE)
75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	0.56 (0.22, 1.41)	
p-value	0.2106	
Relative Risk (95% CI)	0.57 (0.23, 1.43)	
p-value	0.2304	
Odds Ratio (95% CI)	0.56 (0.22, 1.44)	
p-value	0.2295	
Risk Difference (95% CI)	-0.02 (-0.06, 0.01)	
p-value	0.2243	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.7 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of Rituximab



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.7.S Time to first Adverse Event leading to Discontinuation of Rituximab - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.9985
<65	4/ 155 (2.6)	NE (NE , NE)	6/ 137 (4.4)	NE (NE , NE)	0.57 (0.16, 2.02)	0.3755	
>=65	3/ 88 (3.4)	NE (NE , NE)	6/ 101 (5.9)	NE (NE , NE)	0.57 (0.14, 2.26)	0.4134	
Sex							0.4905
Male	3/ 139 (2.2)	NE (NE , NE)	7/ 135 (5.2)	NE (NE , NE)	0.41 (0.10, 1.57)	0.1755	
Female	4/ 104 (3.8)	NE (NE , NE)	5/ 103 (4.9)	NE (NE , NE)	0.78 (0.21, 2.91)	0.7140	
Disease Status 2L							
2L: progression of disease <= 2 years	0/ 63 (0.0)	NE (NE , NE)	4/ 61 (6.6)	NE (NE , NE)			
2L: progression of disease > 2 years	4/ 94 (4.3)	NE (NE , NE)	3/ 94 (3.2)	NE (NE , NE)			
Disease Status 3L+							
3L+: < 6 months	2/ 23 (8.7)	NE (NE , NE)	3/ 22 (13.6)	NE (NE , NE)			
3L+: >= 6 months	1/ 63 (1.6)	NE (NE , NE)	2/ 61 (3.3)	NE (NE , NE)			
Region							0.9906
US/Western Europe	0/ 58 (0.0)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	NE		
Rest of world	7/ 185 (3.8)	NE (NE , NE)	10/ 181 (5.5)	NE (NE , NE)	0.67 (0.25, 1.76)	0.4119	
Number of prior anti-lymphoma therapies							0.9631
2L	4/ 157 (2.5)	NE (NE , NE)	7/ 155 (4.5)	NE (NE , NE)	0.55 (0.16, 1.87)	0.3305	
3L+	3/ 86 (3.5)	NE (NE , NE)	5/ 83 (6.0)	NE (NE , NE)	0.57 (0.14, 2.39)	0.4361	

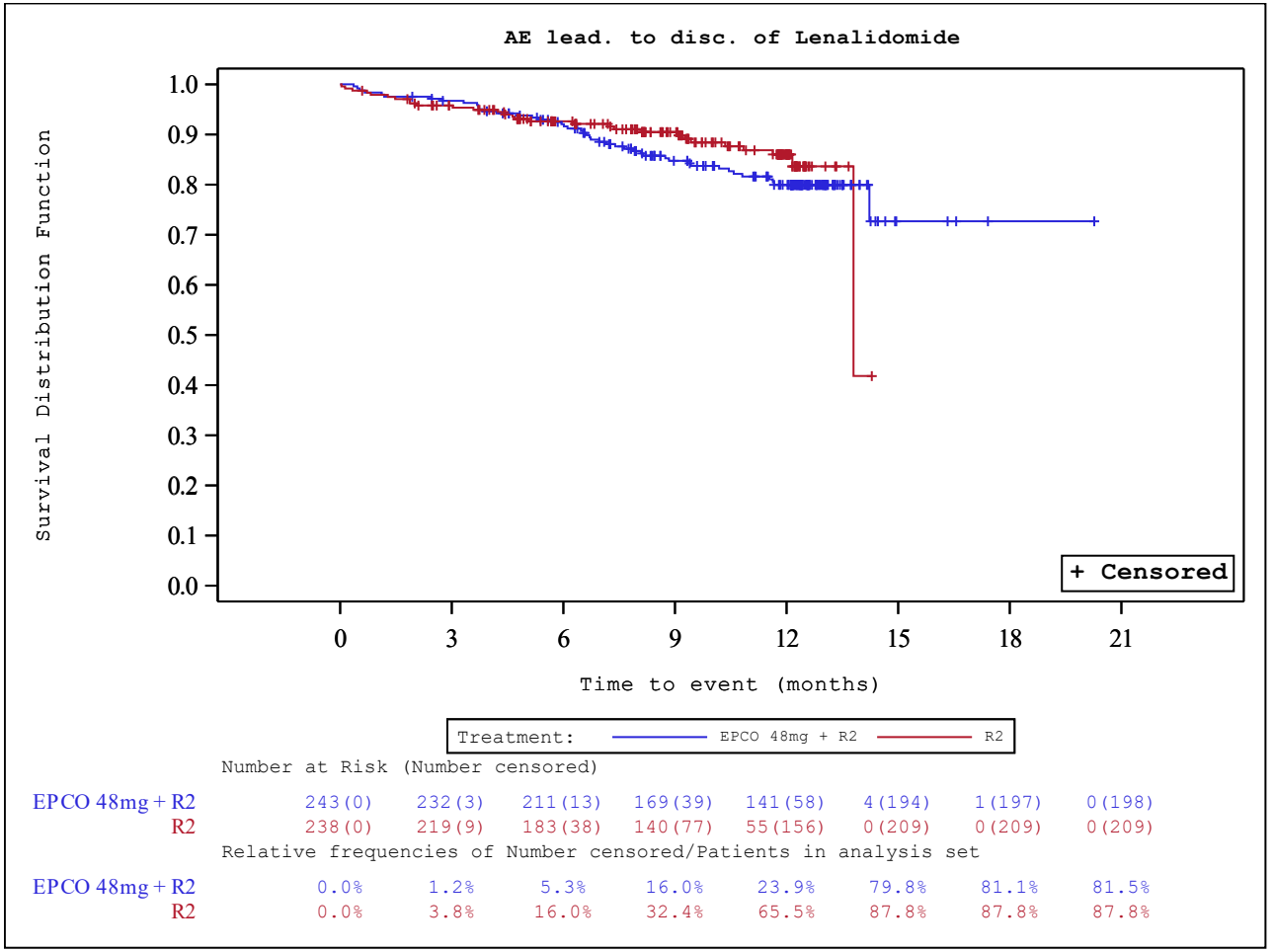
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.8 Time to first Adverse Event leading to Discontinuation of Lenalidomide

	EPCO 48mg + R2	R2
Number of subjects with event, n/N (%)	45/243 (18.5)	29/238 (12.2)
Kaplan-Meier estimates of Time-to-event (months)		
25%-ile (95% CI)	14.23 (11.63, NE)	13.80 (13.80, NE)
Median (95% CI)	NE (NE , NE)	13.80 (13.80, NE)
75%-ile (95% CI)	NE (NE , NE)	NE (13.80, NE)
Analysis EPCO 48mg + R2 vs. R2		
Hazard Ratio (95% CI)	1.29 (0.81, 2.07)	
p-value	0.2805	
Relative Risk (95% CI)	1.52 (0.99, 2.34)	
p-value	0.0571	
Odds Ratio (95% CI)	1.64 (0.99, 2.72)	
p-value	0.0558	
Risk Difference (95% CI)	0.06 (-0.00, 0.13)	
p-value	0.0529	

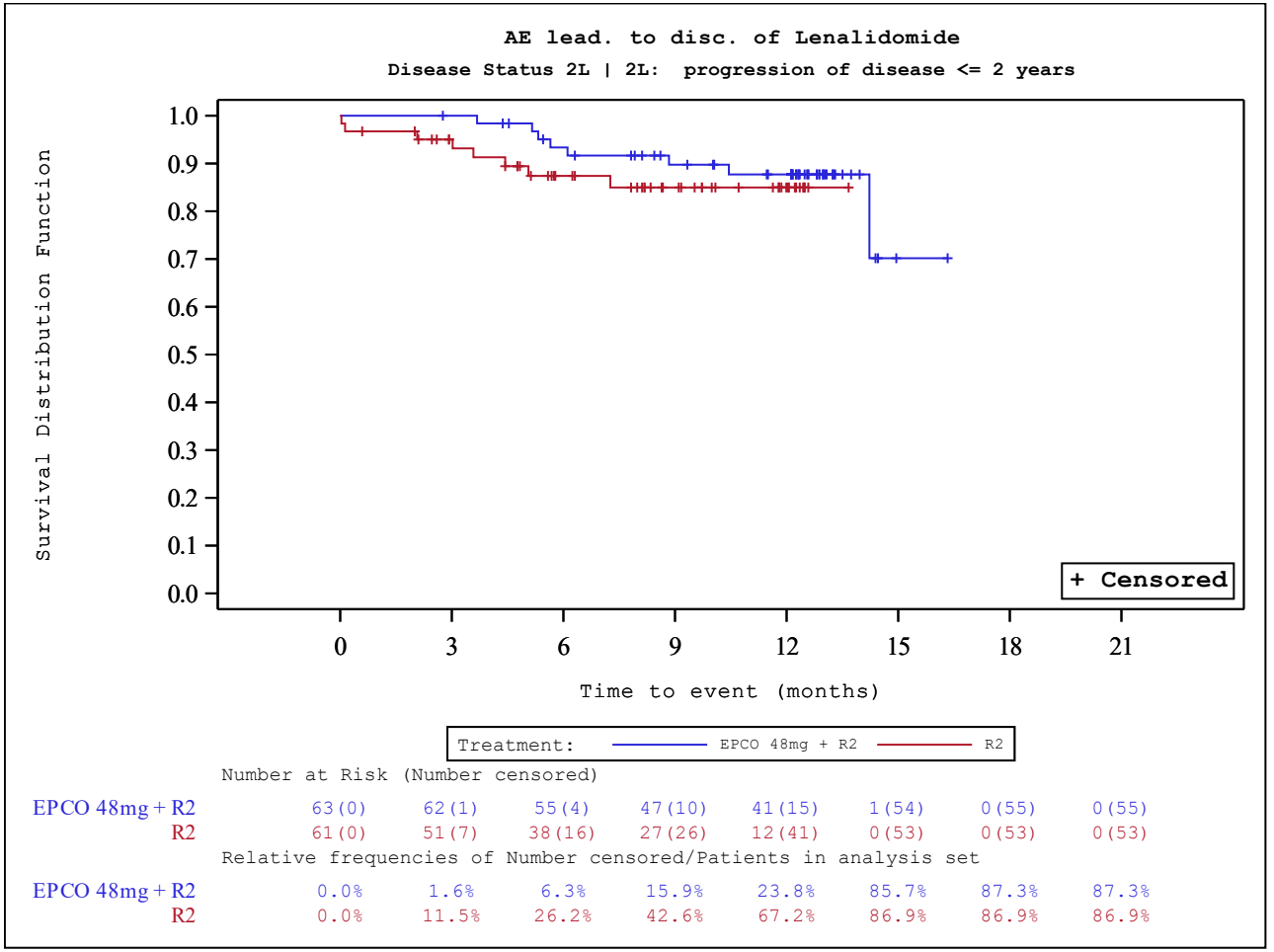
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.8 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of Lenalidomide



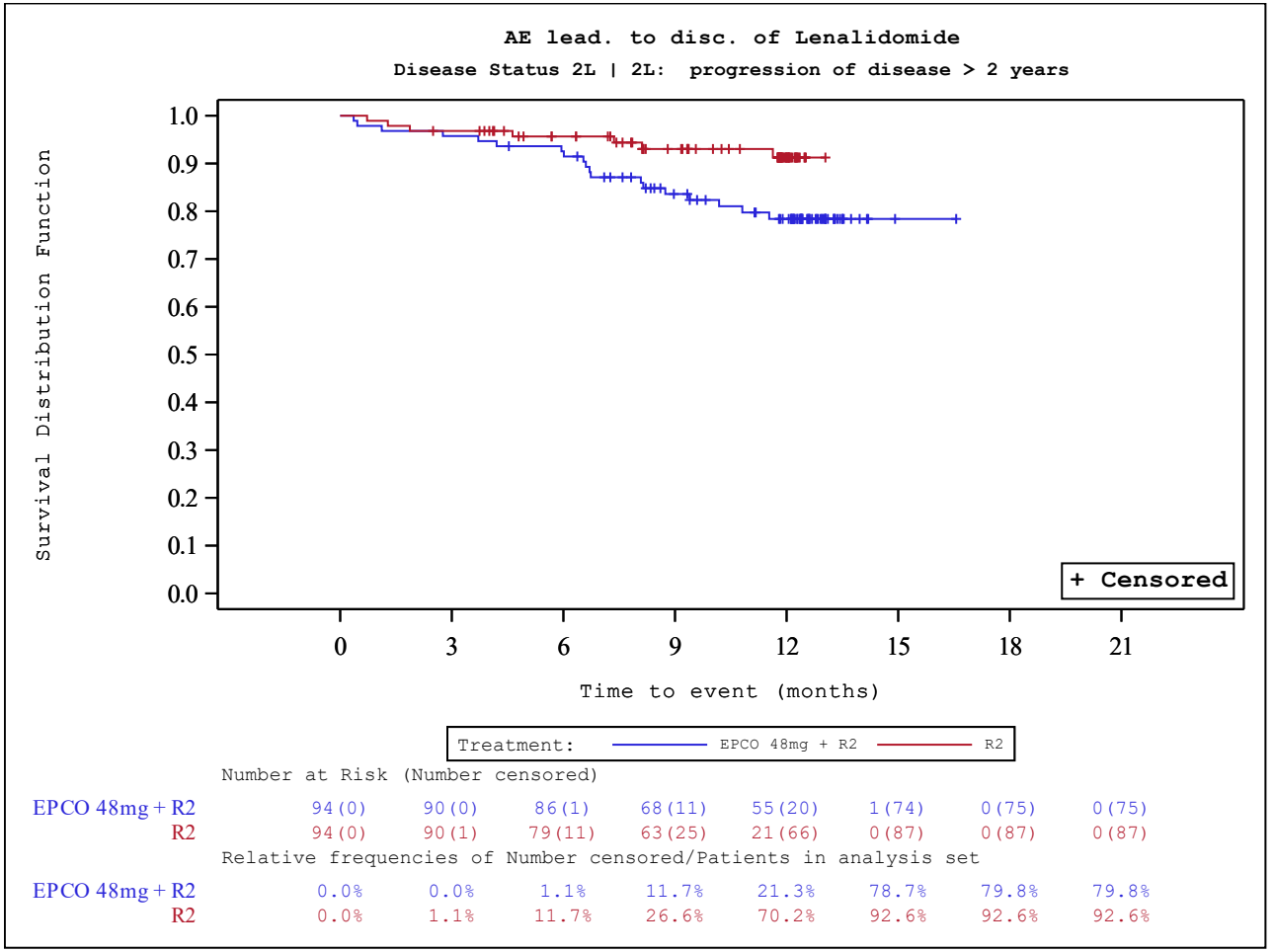
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.1.8 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of Lenalidomide



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.1.8 Kaplan-Meier Plot of Time to first Adverse Event leading to Discontinuation of Lenalidomide



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.1.8.S Time to first Adverse Event leading to Discontinuation of Lenalidomide - Subgroup analysis

Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
Age (years)							0.9100
<65	23/ 155 (14.8)	NE (14.23, NE)	13/ 137 (9.5)	13.80 (NE , NE)	1.27 (0.64, 2.54)	0.4935	
>=65	22/ 88 (25.0)	NE (NE , NE)	16/ 101 (15.8)	NE (NE , NE)	1.42 (0.74, 2.70)	0.2893	
Sex							0.8674
Male	23/ 139 (16.5)	NE (NE , NE)	13/ 135 (9.6)	NE (NE , NE)	1.45 (0.73, 2.87)	0.2832	
Female	22/ 104 (21.2)	NE (14.23, NE)	16/ 103 (15.5)	13.80 (13.80, NE)	1.23 (0.64, 2.36)	0.5279	
Disease Status 2L							0.0473
2L: progression of disease <= 2 years	8/ 63 (12.7)	NE (14.23, NE)	8/ 61 (13.1)	NE (NE , NE)	0.65 (0.24, 1.80)	0.4061	
2L: progression of disease > 2 years	19/ 94 (20.2)	NE (NE , NE)	7/ 94 (7.4)	NE (NE , NE)	2.56 (1.08, 6.09)	0.0276	
Disease Status 3L+							0.7303
3L+: < 6 months	5/ 23 (21.7)	NE (7.92, NE)	3/ 22 (13.6)	NE (NE , NE)	1.59 (0.38, 6.66)	0.5217	
3L+: >= 6 months	13/ 63 (20.6)	NE (NE , NE)	11/ 61 (18.0)	13.80 (13.80, NE)	1.01 (0.45, 2.26)	0.9788	
Region							0.3430
US/Western Europe	12/ 58 (20.7)	NE (NE , NE)	5/ 57 (8.8)	NE (12.16, NE)	2.00 (0.70, 5.69)	0.1872	
Rest of world	33/ 185 (17.8)	NE (NE , NE)	24/ 181 (13.3)	13.80 (13.80, NE)	1.16 (0.68, 1.97)	0.5847	
Number of prior anti-lymphoma therapies							0.6363
2L	27/ 157 (17.2)	NE (14.23, NE)	15/ 155 (9.7)	NE (NE , NE)	1.48 (0.78, 2.80)	0.2223	
3L+	18/ 86 (20.9)	NE (NE , NE)	14/ 83 (16.9)	13.80 (13.80, NE)	1.12 (0.56, 2.26)	0.7476	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders	Number of subjects with events, n/N (%)	168/243 (69.1)	108/238 (45.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	0.72 (0.53, 0.92)	1.84 (1.41, 2.10)
	Median (95% CI)	2.56 (1.94, 3.78)	NE (7.43, NE)
	75%-ile (95% CI)	NE (10.12, NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.81 (1.42, 2.31)	
	p-value	<.0001	
	Relative Risk (95% CI)	1.52 (1.29, 1.79)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.70 (1.86, 3.92)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.24 (0.15, 0.32)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n/N (%)	67/243 (27.6)	41/238 (17.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	8.08 (2.60, NE)	NE (NE , NE)
	Median (95% CI)	NE (14.62, NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.57 (1.06, 2.31)	
	p-value	0.0226	
	Relative Risk (95% CI)	1.60 (1.13, 2.26)	
	p-value	0.0076	
	Odds Ratio (95% CI)	1.83 (1.18, 2.84)	
	p-value	0.0070	
	Risk Difference (95% CI)	0.10 (0.03, 0.18)	
	p-value	0.0061	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Febrile neutropenia	Number of subjects with events, n/N (%)	15/243 (6.2)	6/238 (2.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.29 (0.89, 5.91)	
	p-value	0.0780	
	Relative Risk (95% CI)	2.45 (0.97, 6.20)	
	p-value	0.0591	
	Odds Ratio (95% CI)	2.54 (0.97, 6.67)	
	p-value	0.0577	
	Risk Difference (95% CI)	0.04 (0.00, 0.07)	
	p-value	0.0482	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Leukopenia	Number of subjects with events, n/N (%)	13/243 (5.3)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.20 (0.52, 2.74)	
	p-value	0.6669	
	Relative Risk (95% CI)	1.27 (0.57, 2.85)	
	p-value	0.5563	
	Odds Ratio (95% CI)	1.29 (0.55, 3.00)	
	p-value	0.5561	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.5546	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Lymphopenia	Number of subjects with events, n/N (%)	19/243 (7.8)	9/238 (3.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.02 (0.92, 4.48)	
	p-value	0.0748	
	Relative Risk (95% CI)	2.07 (0.95, 4.48)	
	p-value	0.0654	
	Odds Ratio (95% CI)	2.16 (0.96, 4.87)	
	p-value	0.0640	
	Risk Difference (95% CI)	0.04 (-0.00, 0.08)	
	p-value	0.0569	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Number of subjects with events, n/N (%)	120/243 (49.4)	75/238 (31.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	2.14 (1.64, 2.56)	4.67 (2.79, 7.39)
	Median (95% CI)	10.12 (5.85, NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.70 (1.28, 2.28)	
	p-value	0.0002	
	Relative Risk (95% CI)	1.57 (1.25, 1.97)	
	p-value	0.0001	
	Odds Ratio (95% CI)	2.12 (1.46, 3.07)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.18 (0.09, 0.26)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia	Number of subjects with events, n/N (%)	34/243 (14.0)	33/238 (13.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.96 (0.59, 1.55)	
	p-value	0.8704	
	Relative Risk (95% CI)	1.01 (0.65, 1.57)	
	p-value	0.9681	
	Odds Ratio (95% CI)	1.01 (0.60, 1.69)	
	p-value	0.9681	
	Risk Difference (95% CI)	0.00 (-0.06, 0.06)	
	p-value	0.9681	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Cardiac disorders	Number of subjects with events, n/N (%)	21/243 (8.6)	13/238 (5.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.41 (0.70, 2.82)	
	p-value	0.3302	
	Relative Risk (95% CI)	1.58 (0.81, 3.09)	
	p-value	0.1784	
	Odds Ratio (95% CI)	1.64 (0.80, 3.35)	
	p-value	0.1772	
	Risk Difference (95% CI)	0.03 (-0.01, 0.08)	
	p-value	0.1719	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Ear and labyrinth disorders	Number of subjects with events, n/N (%)	10/243 (4.1)	8/238 (3.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.08 (0.42, 2.74)	
	p-value	0.8761	
	Relative Risk (95% CI)	1.22 (0.49, 3.05)	
	p-value	0.6638	
	Odds Ratio (95% CI)	1.23 (0.48, 3.18)	
	p-value	0.6637	
	Risk Difference (95% CI)	0.01 (-0.03, 0.04)	
	p-value	0.6628	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Eye disorders	Number of subjects with events, n/N (%)	21/243 (8.6)	15/238 (6.3)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.26 (0.65, 2.45)	
	p-value	0.4904	
	Relative Risk (95% CI)	1.37 (0.72, 2.60)	
	p-value	0.3322	
	Odds Ratio (95% CI)	1.41 (0.71, 2.80)	
	p-value	0.3315	
	Risk Difference (95% CI)	0.02 (-0.02, 0.07)	
	p-value	0.3284	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Gastrointestinal disorders	Number of subjects with events, n/N (%)	152/243 (62.6)	135/238 (56.7)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	0.43 (0.26, 0.59)	0.69 (0.49, 1.08)
	Median (95% CI)	3.81 (2.07, 6.60)	6.24 (3.22, 7.59)
	75%-ile (95% CI)	NE (13.14, NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.10 (0.88, 1.39)	
	p-value	0.3993	
	Relative Risk (95% CI)	1.10 (0.95, 1.28)	
	p-value	0.1939	
	Odds Ratio (95% CI)	1.27 (0.88, 1.84)	
	p-value	0.1929	
	Risk Difference (95% CI)	0.06 (-0.03, 0.15)	
	p-value	0.1919	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Gastrointestinal disorders, PT: Abdominal pain	Number of subjects with events, n/N (%)	17/243 (7.0)	15/238 (6.3)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (14.32, NE)	NE (12.45, NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.92 (0.45, 1.88)	
	p-value	0.8194	
	Relative Risk (95% CI)	1.11 (0.57, 2.17)	
	p-value	0.7604	
	Odds Ratio (95% CI)	1.12 (0.55, 2.29)	
	p-value	0.7604	
	Risk Difference (95% CI)	0.01 (-0.04, 0.05)	
	p-value	0.7602	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Gastrointestinal disorders, PT: Constipation	Number of subjects with events, n/N (%)	67/243 (27.6)	51/238 (21.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	2.33 (0.79, NE)	NE (2.33, NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.32 (0.92, 1.90)	
	p-value	0.1338	
	Relative Risk (95% CI)	1.29 (0.94, 1.77)	
	p-value	0.1195	
	Odds Ratio (95% CI)	1.40 (0.92, 2.12)	
	p-value	0.1182	
	Risk Difference (95% CI)	0.06 (-0.02, 0.14)	
	p-value	0.1162	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n/N (%)	75/243 (30.9)	60/238 (25.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	7.39 (5.16, 10.48)	7.56 (5.75, NE)
	Median (95% CI)	NE (14.32, NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.10 (0.79, 1.55)	
	p-value	0.5663	
	Relative Risk (95% CI)	1.22 (0.92, 1.63)	
	p-value	0.1694	
	Odds Ratio (95% CI)	1.32 (0.89, 1.98)	
	p-value	0.1682	
	Risk Difference (95% CI)	0.06 (-0.02, 0.14)	
	p-value	0.1665	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n/N (%)	41/243 (16.9)	28/238 (11.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (12.68, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.33 (0.82, 2.16)	
	p-value	0.2420	
	Relative Risk (95% CI)	1.43 (0.92, 2.24)	
	p-value	0.1131	
	Odds Ratio (95% CI)	1.52 (0.91, 2.56)	
	p-value	0.1118	
	Risk Difference (95% CI)	0.05 (-0.01, 0.11)	
	p-value	0.1086	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n/N (%)	11/243 (4.5)	7/238 (2.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.42 (0.55, 3.66)	
	p-value	0.4693	
	Relative Risk (95% CI)	1.54 (0.61, 3.90)	
	p-value	0.3638	
	Odds Ratio (95% CI)	1.56 (0.60, 4.11)	
	p-value	0.3632	
	Risk Difference (95% CI)	0.02 (-0.02, 0.05)	
	p-value	0.3582	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions	Number of subjects with events, n/N (%)	164/243 (67.5)	101/238 (42.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	0.66 (0.53, 0.89)	0.82 (0.49, 1.68)
	Median (95% CI)	1.68 (1.25, 2.14)	NE (8.54, NE)
	75%-ile (95% CI)	NE (13.24, NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.82 (1.42, 2.33)	
	p-value	<.0001	
	Relative Risk (95% CI)	1.59 (1.34, 1.89)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.82 (1.94, 4.08)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.25 (0.16, 0.34)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions, PT: Asthenia	Number of subjects with events, n/N (%)	30/243 (12.3)	24/238 (10.1)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.13 (0.66, 1.93)	
	p-value	0.6586	
	Relative Risk (95% CI)	1.22 (0.74, 2.03)	
	p-value	0.4333	
	Odds Ratio (95% CI)	1.26 (0.71, 2.22)	
	p-value	0.4328	
	Risk Difference (95% CI)	0.02 (-0.03, 0.08)	
	p-value	0.4314	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n/N (%)	48/243 (19.8)	31/238 (13.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (8.38, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.50 (0.95, 2.35)	
	p-value	0.0778	
	Relative Risk (95% CI)	1.52 (1.00, 2.30)	
	p-value	0.0491	
	Odds Ratio (95% CI)	1.64 (1.00, 2.69)	
	p-value	0.0478	
	Risk Difference (95% CI)	0.07 (0.00, 0.13)	
	p-value	0.0452	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions, PT: Injection site erythema	Number of subjects with events, n/N (%)	13/243 (5.3)	0/238 (0.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	NE	
	p-value		
	Relative Risk (95% CI)	26.45 (1.58, 442.38)	
	p-value	0.0227	
	Odds Ratio (95% CI)	27.94 (1.65, 472.68)	
	p-value	0.0210	
	Risk Difference (95% CI)	0.05 (0.03, 0.08)	
	p-value	0.0002	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions, PT: Injection site reaction	Number of subjects with events, n/N (%)	53/243 (21.8)	0/238 (0.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (2.17, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	NE	
	p-value		
	Relative Risk (95% CI)	104.81 (6.51, 1687.72)	
	p-value	0.0010	
	Odds Ratio (95% CI)	133.96 (8.22, 2183.71)	
	p-value	0.0006	
	Risk Difference (95% CI)	0.22 (0.17, 0.27)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions, PT: Oedema peripheral	Number of subjects with events, n/N (%)	21/243 (8.6)	16/238 (6.7)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.24 (0.65, 2.38)	
	p-value	0.5162	
	Relative Risk (95% CI)	1.29 (0.69, 2.40)	
	p-value	0.4312	
	Odds Ratio (95% CI)	1.31 (0.67, 2.58)	
	p-value	0.4308	
	Risk Difference (95% CI)	0.02 (-0.03, 0.07)	
	p-value	0.4288	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions, PT: Pyrexia	Number of subjects with events, n/N (%)	58/243 (23.9)	33/238 (13.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (3.45, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.70 (1.11, 2.61)	
	p-value	0.0134	
	Relative Risk (95% CI)	1.72 (1.17, 2.54)	
	p-value	0.0061	
	Odds Ratio (95% CI)	1.95 (1.22, 3.12)	
	p-value	0.0056	
	Risk Difference (95% CI)	0.10 (0.03, 0.17)	
	p-value	0.0047	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Hepatobiliary disorders	Number of subjects with events, n/N (%)	12/243 (4.9)	2/238 (0.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	5.38 (1.20, 24.12)	
	p-value	0.0137	
	Relative Risk (95% CI)	5.88 (1.33, 25.98)	
	p-value	0.0195	
	Odds Ratio (95% CI)	6.13 (1.36, 27.69)	
	p-value	0.0184	
	Risk Difference (95% CI)	0.04 (0.01, 0.07)	
	p-value	0.0067	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Immune system disorders	Number of subjects with events, n/N (%)	115/243 (47.3)	18/238 (7.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	0.72 (0.59, 0.89)	NE (NE , NE)
	Median (95% CI)	13.04 (6.74, NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	7.68 (4.67, 12.63)	
	p-value	<.0001	
	Relative Risk (95% CI)	6.26 (3.94, 9.95)	
	p-value	<.0001	
	Odds Ratio (95% CI)	10.98 (6.38, 18.89)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.40 (0.33, 0.47)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Immune system disorders, PT: Cytokine release syndrome	Number of subjects with events, n/N (%)	85/243 (35.0)	1/238 (0.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	0.76 (0.59, 0.92)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	100.16 (13.95, 719.30)	
	p-value	<.0001	
	Relative Risk (95% CI)	83.25 (11.69, 593.00)	
	p-value	<.0001	
	Odds Ratio (95% CI)	127.50 (17.57, 925.03)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.35 (0.29, 0.41)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Immune system disorders, PT: Hypogammaglobulinaemia	Number of subjects with events, n/N (%)	47/243 (19.3)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (10.45, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	4.51 (2.28, 8.92)	
	p-value	<.0001	
	Relative Risk (95% CI)	4.60 (2.38, 8.90)	
	p-value	<.0001	
	Odds Ratio (95% CI)	5.47 (2.69, 11.11)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.15 (0.10, 0.21)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations	Number of subjects with events, n/N (%)	188/243 (77.4)	125/238 (52.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	0.92 (0.72, 1.25)	2.37 (1.54, 3.29)
	Median (95% CI)	2.79 (2.33, 3.65)	7.66 (5.65, 9.92)
	75%-ile (95% CI)	9.43 (6.87, 11.47)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.77 (1.41, 2.22)	
	p-value	<.0001	
	Relative Risk (95% CI)	1.47 (1.28, 1.69)	
	p-value	<.0001	
	Odds Ratio (95% CI)	3.09 (2.08, 4.58)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.25 (0.17, 0.33)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n/N (%)	13/243 (5.3)	3/238 (1.3)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	3.79 (1.08, 13.31)	
	p-value	0.0255	
	Relative Risk (95% CI)	4.24 (1.23, 14.70)	
	p-value	0.0226	
	Odds Ratio (95% CI)	4.43 (1.25, 15.74)	
	p-value	0.0215	
	Risk Difference (95% CI)	0.04 (0.01, 0.07)	
	p-value	0.0113	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: COVID-19	Number of subjects with events, n/N (%)	54/243 (22.2)	32/238 (13.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	12.29 (9.26, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.47 (0.95, 2.28)	
	p-value	0.0840	
	Relative Risk (95% CI)	1.65 (1.11, 2.46)	
	p-value	0.0136	
	Odds Ratio (95% CI)	1.84 (1.14, 2.97)	
	p-value	0.0128	
	Risk Difference (95% CI)	0.09 (0.02, 0.16)	
	p-value	0.0113	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: COVID-19 pneumonia	Number of subjects with events, n/N (%)	11/243 (4.5)	1/238 (0.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (14.23, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	8.82 (1.13, 68.87)	
	p-value	0.0122	
	Relative Risk (95% CI)	10.77 (1.40, 82.80)	
	p-value	0.0223	
	Odds Ratio (95% CI)	11.24 (1.44, 87.74)	
	p-value	0.0210	
	Risk Difference (95% CI)	0.04 (0.01, 0.07)	
	p-value	0.0033	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n/N (%)	13/243 (5.3)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	16.53 (16.53, NE)	NE (NE , NE)
	Median (95% CI)	NE (16.53, NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (16.53, NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.99 (0.43, 2.30)	
	p-value	0.9800	
	Relative Risk (95% CI)	1.27 (0.57, 2.85)	
	p-value	0.5563	
	Odds Ratio (95% CI)	1.29 (0.55, 3.00)	
	p-value	0.5561	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.5546	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n/N (%)	47/243 (19.3)	20/238 (8.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (10.45, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.07 (1.23, 3.50)	
	p-value	0.0053	
	Relative Risk (95% CI)	2.30 (1.41, 3.76)	
	p-value	0.0009	
	Odds Ratio (95% CI)	2.61 (1.50, 4.57)	
	p-value	0.0007	
	Risk Difference (95% CI)	0.11 (0.05, 0.17)	
	p-value	0.0004	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Respiratory tract infection	Number of subjects with events, n/N (%)	16/243 (6.6)	9/238 (3.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.59 (0.70, 3.60)	
	p-value	0.2618	
	Relative Risk (95% CI)	1.74 (0.78, 3.86)	
	p-value	0.1726	
	Odds Ratio (95% CI)	1.79 (0.78, 4.14)	
	p-value	0.1714	
	Risk Difference (95% CI)	0.03 (-0.01, 0.07)	
	p-value	0.1642	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Rhinovirus infection	Number of subjects with events, n/N (%)	12/243 (4.9)	2/238 (0.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	5.52 (1.24, 24.70)	
	p-value	0.0118	
	Relative Risk (95% CI)	5.88 (1.33, 25.98)	
	p-value	0.0195	
	Odds Ratio (95% CI)	6.13 (1.36, 27.69)	
	p-value	0.0184	
	Risk Difference (95% CI)	0.04 (0.01, 0.07)	
	p-value	0.0067	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n/N (%)	15/243 (6.2)	5/238 (2.1)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.37 (0.86, 6.59)	
	p-value	0.0872	
	Relative Risk (95% CI)	2.94 (1.09, 7.96)	
	p-value	0.0340	
	Odds Ratio (95% CI)	3.07 (1.10, 8.57)	
	p-value	0.0328	
	Risk Difference (95% CI)	0.04 (0.01, 0.08)	
	p-value	0.0238	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n/N (%)	49/243 (20.2)	33/238 (13.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (9.72, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.32 (0.85, 2.05)	
	p-value	0.2216	
	Relative Risk (95% CI)	1.45 (0.97, 2.18)	
	p-value	0.0689	
	Odds Ratio (95% CI)	1.57 (0.97, 2.54)	
	p-value	0.0676	
	Risk Difference (95% CI)	0.06 (-0.00, 0.13)	
	p-value	0.0649	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n/N (%)	13/243 (5.3)	9/238 (3.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.25 (0.53, 2.94)	
	p-value	0.6044	
	Relative Risk (95% CI)	1.41 (0.62, 3.25)	
	p-value	0.4131	
	Odds Ratio (95% CI)	1.44 (0.60, 3.43)	
	p-value	0.4127	
	Risk Difference (95% CI)	0.02 (-0.02, 0.05)	
	p-value	0.4093	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n/N (%)	60/243 (24.7)	40/238 (16.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	12.32 (4.93, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.38 (0.92, 2.06)	
	p-value	0.1063	
	Relative Risk (95% CI)	1.47 (1.03, 2.10)	
	p-value	0.0352	
	Odds Ratio (95% CI)	1.62 (1.04, 2.54)	
	p-value	0.0340	
	Risk Difference (95% CI)	0.08 (0.01, 0.15)	
	p-value	0.0321	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n/N (%)	32/243 (13.2)	31/238 (13.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.01 (0.61, 1.65)	
	p-value	0.9830	
	Relative Risk (95% CI)	1.01 (0.64, 1.60)	
	p-value	0.9628	
	Odds Ratio (95% CI)	1.01 (0.60, 1.72)	
	p-value	0.9628	
	Risk Difference (95% CI)	0.00 (-0.06, 0.06)	
	p-value	0.9628	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations	Number of subjects with events, n/N (%)	151/243 (62.1)	94/238 (39.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	0.56 (0.49, 0.76)	1.84 (0.72, 2.83)
	Median (95% CI)	3.78 (1.87, 7.36)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.77 (1.37, 2.29)	
	p-value	<.0001	
	Relative Risk (95% CI)	1.57 (1.31, 1.89)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.51 (1.74, 3.63)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.23 (0.14, 0.31)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Alanine aminotransferase increased	Number of subjects with events, n/N (%)	46/243 (18.9)	23/238 (9.7)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (12.19, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.86 (1.13, 3.08)	
	p-value	0.0132	
	Relative Risk (95% CI)	1.96 (1.23, 3.13)	
	p-value	0.0048	
	Odds Ratio (95% CI)	2.18 (1.28, 3.73)	
	p-value	0.0044	
	Risk Difference (95% CI)	0.09 (0.03, 0.15)	
	p-value	0.0034	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Aspartate aminotransferase increased	Number of subjects with events, n/N (%)	29/243 (11.9)	15/238 (6.3)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.84 (0.99, 3.43)	
	p-value	0.0516	
	Relative Risk (95% CI)	1.89 (1.04, 3.44)	
	p-value	0.0361	
	Odds Ratio (95% CI)	2.01 (1.05, 3.86)	
	p-value	0.0349	
	Risk Difference (95% CI)	0.06 (0.01, 0.11)	
	p-value	0.0309	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Blood bilirubin increased	Number of subjects with events, n/N (%)	7/243 (2.9)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.65 (0.25, 1.72)	
	p-value	0.3836	
	Relative Risk (95% CI)	0.69 (0.27, 1.77)	
	p-value	0.4357	
	Odds Ratio (95% CI)	0.68 (0.25, 1.81)	
	p-value	0.4354	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.02)	
	p-value	0.4333	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Blood creatinine increased	Number of subjects with events, n/N (%)	20/243 (8.2)	8/238 (3.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.41 (1.06, 5.48)	
	p-value	0.0297	
	Relative Risk (95% CI)	2.45 (1.10, 5.45)	
	p-value	0.0283	
	Odds Ratio (95% CI)	2.58 (1.11, 5.97)	
	p-value	0.0272	
	Risk Difference (95% CI)	0.05 (0.01, 0.09)	
	p-value	0.0213	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Blood lactate dehydrogenase increased	Number of subjects with events, n/N (%)	10/243 (4.1)	5/238 (2.1)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.89 (0.65, 5.55)	
	p-value	0.2354	
	Relative Risk (95% CI)	1.96 (0.68, 5.65)	
	p-value	0.2132	
	Odds Ratio (95% CI)	2.00 (0.67, 5.94)	
	p-value	0.2121	
	Risk Difference (95% CI)	0.02 (-0.01, 0.05)	
	p-value	0.2016	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: C-reactive protein increased	Number of subjects with events, n/N (%)	17/243 (7.0)	9/238 (3.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.82 (0.81, 4.08)	
	p-value	0.1404	
	Relative Risk (95% CI)	1.85 (0.84, 4.07)	
	p-value	0.1259	
	Odds Ratio (95% CI)	1.91 (0.84, 4.38)	
	p-value	0.1246	
	Risk Difference (95% CI)	0.03 (-0.01, 0.07)	
	p-value	0.1171	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Gamma-glutamyltransferase increased	Number of subjects with events, n/N (%)	12/243 (4.9)	0/238 (0.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	NE	
	p-value		
	Relative Risk (95% CI)	24.49 (1.46, 411.27)	
	p-value	0.0263	
	Odds Ratio (95% CI)	25.76 (1.52, 437.53)	
	p-value	0.0246	
	Risk Difference (95% CI)	0.05 (0.02, 0.08)	
	p-value	0.0004	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Lymphocyte count decreased	Number of subjects with events, n/N (%)	23/243 (9.5)	16/238 (6.7)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.37 (0.73, 2.60)	
	p-value	0.3271	
	Relative Risk (95% CI)	1.41 (0.76, 2.60)	
	p-value	0.2736	
	Odds Ratio (95% CI)	1.45 (0.75, 2.82)	
	p-value	0.2728	
	Risk Difference (95% CI)	0.03 (-0.02, 0.08)	
	p-value	0.2692	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Neutrophil count decreased	Number of subjects with events, n/N (%)	65/243 (26.7)	50/238 (21.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	5.59 (3.02, NE)	NE (5.59, NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.26 (0.87, 1.83)	
	p-value	0.2140	
	Relative Risk (95% CI)	1.27 (0.92, 1.76)	
	p-value	0.1420	
	Odds Ratio (95% CI)	1.37 (0.90, 2.09)	
	p-value	0.1408	
	Risk Difference (95% CI)	0.06 (-0.02, 0.13)	
	p-value	0.1388	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Platelet count decreased	Number of subjects with events, n/N (%)	35/243 (14.4)	13/238 (5.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.67 (1.41, 5.04)	
	p-value	0.0017	
	Relative Risk (95% CI)	2.64 (1.43, 4.86)	
	p-value	0.0019	
	Odds Ratio (95% CI)	2.91 (1.50, 5.66)	
	p-value	0.0016	
	Risk Difference (95% CI)	0.09 (0.04, 0.14)	
	p-value	0.0009	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Weight decreased	Number of subjects with events, n/N (%)	24/243 (9.9)	7/238 (2.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	3.16 (1.36, 7.34)	
	p-value	0.0047	
	Relative Risk (95% CI)	3.36 (1.47, 7.65)	
	p-value	0.0039	
	Odds Ratio (95% CI)	3.62 (1.53, 8.56)	
	p-value	0.0035	
	Risk Difference (95% CI)	0.07 (0.03, 0.11)	
	p-value	0.0017	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: White blood cell count decreased	Number of subjects with events, n/N (%)	32/243 (13.2)	29/238 (12.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.00 (0.61, 1.66)	
	p-value	0.9899	
	Relative Risk (95% CI)	1.08 (0.68, 1.73)	
	p-value	0.7459	
	Odds Ratio (95% CI)	1.09 (0.64, 1.87)	
	p-value	0.7458	
	Risk Difference (95% CI)	0.01 (-0.05, 0.07)	
	p-value	0.7457	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Metabolism and nutrition disorders	Number of subjects with events, n/N (%)	102/243 (42.0)	66/238 (27.7)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	0.99 (0.76, 2.14)	5.75 (2.33, NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.60 (1.17, 2.18)	
	p-value	0.0026	
	Relative Risk (95% CI)	1.51 (1.18, 1.95)	
	p-value	0.0013	
	Odds Ratio (95% CI)	1.89 (1.29, 2.76)	
	p-value	0.0011	
	Risk Difference (95% CI)	0.14 (0.06, 0.23)	
	p-value	0.0009	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Number of subjects with events, n/N (%)	14/243 (5.8)	18/238 (7.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.70 (0.35, 1.41)	
	p-value	0.3154	
	Relative Risk (95% CI)	0.76 (0.39, 1.50)	
	p-value	0.4296	
	Odds Ratio (95% CI)	0.75 (0.36, 1.54)	
	p-value	0.4292	
	Risk Difference (95% CI)	-0.02 (-0.06, 0.03)	
	p-value	0.4282	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Metabolism and nutrition disorders, PT: Hyperglycaemia	Number of subjects with events, n/N (%)	17/243 (7.0)	7/238 (2.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.40 (0.99, 5.78)	
	p-value	0.0443	
	Relative Risk (95% CI)	2.38 (1.00, 5.63)	
	p-value	0.0488	
	Odds Ratio (95% CI)	2.48 (1.01, 6.10)	
	p-value	0.0475	
	Risk Difference (95% CI)	0.04 (0.00, 0.08)	
	p-value	0.0395	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Metabolism and nutrition disorders, PT: Hypertriglyceridaemia	Number of subjects with events, n/N (%)	20/243 (8.2)	7/238 (2.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.70 (1.14, 6.39)	
	p-value	0.0186	
	Relative Risk (95% CI)	2.80 (1.21, 6.49)	
	p-value	0.0166	
	Odds Ratio (95% CI)	2.96 (1.23, 7.14)	
	p-value	0.0157	
	Risk Difference (95% CI)	0.05 (0.01, 0.09)	
	p-value	0.0108	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Number of subjects with events, n/N (%)	48/243 (19.8)	21/238 (8.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (11.30, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.21 (1.32, 3.70)	
	p-value	0.0018	
	Relative Risk (95% CI)	2.24 (1.38, 3.62)	
	p-value	0.0010	
	Odds Ratio (95% CI)	2.54 (1.47, 4.40)	
	p-value	0.0008	
	Risk Difference (95% CI)	0.11 (0.05, 0.17)	
	p-value	0.0005	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Metabolism and nutrition disorders, PT: Hypomagnesaemia	Number of subjects with events, n/N (%)	15/243 (6.2)	6/238 (2.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.26 (0.87, 5.83)	
	p-value	0.0836	
	Relative Risk (95% CI)	2.45 (0.97, 6.20)	
	p-value	0.0591	
	Odds Ratio (95% CI)	2.54 (0.97, 6.67)	
	p-value	0.0577	
	Risk Difference (95% CI)	0.04 (0.00, 0.07)	
	p-value	0.0482	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n/N (%)	79/243 (32.5)	76/238 (31.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	2.86 (1.35, 7.39)	3.81 (2.04, 6.74)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.98 (0.72, 1.34)	
	p-value	0.9063	
	Relative Risk (95% CI)	1.02 (0.79, 1.32)	
	p-value	0.8922	
	Odds Ratio (95% CI)	1.03 (0.70, 1.51)	
	p-value	0.8922	
	Risk Difference (95% CI)	0.01 (-0.08, 0.09)	
	p-value	0.8922	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n/N (%)	20/243 (8.2)	13/238 (5.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.40 (0.70, 2.83)	
	p-value	0.3389	
	Relative Risk (95% CI)	1.51 (0.77, 2.96)	
	p-value	0.2339	
	Odds Ratio (95% CI)	1.55 (0.75, 3.20)	
	p-value	0.2329	
	Risk Difference (95% CI)	0.03 (-0.02, 0.07)	
	p-value	0.2282	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n/N (%)	12/243 (4.9)	14/238 (5.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.76 (0.35, 1.64)	
	p-value	0.4834	
	Relative Risk (95% CI)	0.84 (0.40, 1.78)	
	p-value	0.6476	
	Odds Ratio (95% CI)	0.83 (0.38, 1.84)	
	p-value	0.6475	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.03)	
	p-value	0.6473	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Musculoskeletal and connective tissue disorders, PT: Muscle spasms	Number of subjects with events, n/N (%)	37/243 (15.2)	27/238 (11.3)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.30 (0.79, 2.13)	
	p-value	0.3027	
	Relative Risk (95% CI)	1.34 (0.84, 2.13)	
	p-value	0.2126	
	Odds Ratio (95% CI)	1.40 (0.82, 2.39)	
	p-value	0.2116	
	Risk Difference (95% CI)	0.04 (-0.02, 0.10)	
	p-value	0.2088	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia	Number of subjects with events, n/N (%)	12/243 (4.9)	7/238 (2.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.64 (0.64, 4.16)	
	p-value	0.2963	
	Relative Risk (95% CI)	1.68 (0.67, 4.19)	
	p-value	0.2669	
	Odds Ratio (95% CI)	1.71 (0.66, 4.43)	
	p-value	0.2660	
	Risk Difference (95% CI)	0.02 (-0.01, 0.05)	
	p-value	0.2591	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n/N (%)	17/243 (7.0)	17/238 (7.1)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (13.80, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.88 (0.45, 1.74)	
	p-value	0.7115	
	Relative Risk (95% CI)	0.98 (0.51, 1.87)	
	p-value	0.9499	
	Odds Ratio (95% CI)	0.98 (0.49, 1.96)	
	p-value	0.9499	
	Risk Difference (95% CI)	-0.00 (-0.05, 0.04)	
	p-value	0.9499	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Nervous system disorders	Number of subjects with events, n/N (%)	90/243 (37.0)	59/238 (24.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	1.81 (0.92, 3.98)	7.89 (3.88, NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.56 (1.12, 2.16)	
	p-value	0.0075	
	Relative Risk (95% CI)	1.49 (1.13, 1.97)	
	p-value	0.0043	
	Odds Ratio (95% CI)	1.78 (1.20, 2.64)	
	p-value	0.0039	
	Risk Difference (95% CI)	0.12 (0.04, 0.20)	
	p-value	0.0034	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Nervous system disorders, PT: Dizziness	Number of subjects with events, n/N (%)	19/243 (7.8)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.82 (0.85, 3.92)	
	p-value	0.1195	
	Relative Risk (95% CI)	1.86 (0.88, 3.92)	
	p-value	0.1021	
	Odds Ratio (95% CI)	1.93 (0.88, 4.25)	
	p-value	0.1007	
	Risk Difference (95% CI)	0.04 (-0.01, 0.08)	
	p-value	0.0937	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n/N (%)	27/243 (11.1)	9/238 (3.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.83 (1.33, 6.02)	
	p-value	0.0047	
	Relative Risk (95% CI)	2.94 (1.41, 6.11)	
	p-value	0.0039	
	Odds Ratio (95% CI)	3.18 (1.46, 6.92)	
	p-value	0.0035	
	Risk Difference (95% CI)	0.07 (0.03, 0.12)	
	p-value	0.0019	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Nervous system disorders, PT: Neuropathy peripheral	Number of subjects with events, n/N (%)	7/243 (2.9)	13/238 (5.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.48 (0.19, 1.20)	
	p-value	0.1093	
	Relative Risk (95% CI)	0.53 (0.21, 1.30)	
	p-value	0.1641	
	Odds Ratio (95% CI)	0.51 (0.20, 1.31)	
	p-value	0.1630	
	Risk Difference (95% CI)	-0.03 (-0.06, 0.01)	
	p-value	0.1566	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Nervous system disorders, PT: Peripheral sensory neuropathy	Number of subjects with events, n/N (%)	11/243 (4.5)	5/238 (2.1)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.01 (0.70, 5.80)	
	p-value	0.1855	
	Relative Risk (95% CI)	2.15 (0.76, 6.11)	
	p-value	0.1487	
	Odds Ratio (95% CI)	2.21 (0.76, 6.46)	
	p-value	0.1475	
	Risk Difference (95% CI)	0.02 (-0.01, 0.06)	
	p-value	0.1356	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Nervous system disorders, PT: Tremor	Number of subjects with events, n/N (%)	20/243 (8.2)	2/238 (0.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	10.05 (2.35, 42.98)	
	p-value	0.0001	
	Relative Risk (95% CI)	9.79 (2.31, 41.44)	
	p-value	0.0019	
	Odds Ratio (95% CI)	10.58 (2.45, 45.80)	
	p-value	0.0016	
	Risk Difference (95% CI)	0.07 (0.04, 0.11)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Psychiatric disorders	Number of subjects with events, n/N (%)	46/243 (18.9)	14/238 (5.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (11.30, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	3.33 (1.83, 6.06)	
	p-value	<.0001	
	Relative Risk (95% CI)	3.22 (1.82, 5.70)	
	p-value	<.0001	
	Odds Ratio (95% CI)	3.74 (1.99, 7.00)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.13 (0.07, 0.19)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n/N (%)	35/243 (14.4)	8/238 (3.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	4.44 (2.06, 9.57)	
	p-value	<.0001	
	Relative Risk (95% CI)	4.28 (2.03, 9.04)	
	p-value	0.0001	
	Odds Ratio (95% CI)	4.84 (2.19, 10.67)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.11 (0.06, 0.16)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Renal and urinary disorders	Number of subjects with events, n/N (%)	29/243 (11.9)	18/238 (7.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.42 (0.78, 2.56)	
	p-value	0.2458	
	Relative Risk (95% CI)	1.58 (0.90, 2.76)	
	p-value	0.1106	
	Odds Ratio (95% CI)	1.66 (0.89, 3.07)	
	p-value	0.1093	
	Risk Difference (95% CI)	0.04 (-0.01, 0.10)	
	p-value	0.1048	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n/N (%)	98/243 (40.3)	61/238 (25.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	4.67 (2.23, 6.31)	7.43 (5.09, NE)
	Median (95% CI)	NE (12.45, NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.51 (1.10, 2.08)	
	p-value	0.0111	
	Relative Risk (95% CI)	1.57 (1.21, 2.05)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.96 (1.33, 2.89)	
	p-value	0.0007	
	Risk Difference (95% CI)	0.15 (0.06, 0.23)	
	p-value	0.0005	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n/N (%)	47/243 (19.3)	25/238 (10.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (10.48, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.66 (1.02, 2.69)	
	p-value	0.0398	
	Relative Risk (95% CI)	1.84 (1.17, 2.89)	
	p-value	0.0080	
	Odds Ratio (95% CI)	2.04 (1.21, 3.45)	
	p-value	0.0074	
	Risk Difference (95% CI)	0.09 (0.03, 0.15)	
	p-value	0.0061	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea	Number of subjects with events, n/N (%)	13/243 (5.3)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.24 (0.54, 2.83)	
	p-value	0.6052	
	Relative Risk (95% CI)	1.27 (0.57, 2.85)	
	p-value	0.5563	
	Odds Ratio (95% CI)	1.29 (0.55, 3.00)	
	p-value	0.5561	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.5546	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain	Number of subjects with events, n/N (%)	11/243 (4.5)	2/238 (0.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	5.31 (1.18, 23.97)	
	p-value	0.0149	
	Relative Risk (95% CI)	5.39 (1.21, 24.05)	
	p-value	0.0274	
	Odds Ratio (95% CI)	5.59 (1.23, 25.52)	
	p-value	0.0262	
	Risk Difference (95% CI)	0.04 (0.01, 0.07)	
	p-value	0.0115	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Respiratory, thoracic and mediastinal disorders, PT: Pleural effusion	Number of subjects with events, n/N (%)	9/243 (3.7)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.79 (0.32, 1.96)	
	p-value	0.6152	
	Relative Risk (95% CI)	0.88 (0.36, 2.13)	
	p-value	0.7794	
	Odds Ratio (95% CI)	0.88 (0.35, 2.20)	
	p-value	0.7794	
	Risk Difference (95% CI)	-0.00 (-0.04, 0.03)	
	p-value	0.7793	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n/N (%)	134/243 (55.1)	118/238 (49.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	1.28 (0.89, 1.81)	0.33 (0.26, 0.53)
	Median (95% CI)	6.11 (4.14, 10.38)	8.61 (3.15, NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.96 (0.75, 1.23)	
	p-value	0.7240	
	Relative Risk (95% CI)	1.11 (0.94, 1.32)	
	p-value	0.2231	
	Odds Ratio (95% CI)	1.25 (0.87, 1.79)	
	p-value	0.2221	
	Risk Difference (95% CI)	0.06 (-0.03, 0.14)	
	p-value	0.2211	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Skin and subcutaneous tissue disorders, PT: Dry skin	Number of subjects with events, n/N (%)	11/243 (4.5)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.99 (0.42, 2.34)	
	p-value	0.9899	
	Relative Risk (95% CI)	1.08 (0.47, 2.49)	
	p-value	0.8616	
	Odds Ratio (95% CI)	1.08 (0.45, 2.59)	
	p-value	0.8615	
	Risk Difference (95% CI)	0.00 (-0.03, 0.04)	
	p-value	0.8615	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Skin and subcutaneous tissue disorders, PT: Erythema	Number of subjects with events, n/N (%)	18/243 (7.4)	7/238 (2.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.35 (0.98, 5.63)	
	p-value	0.0485	
	Relative Risk (95% CI)	2.52 (1.07, 5.92)	
	p-value	0.0341	
	Odds Ratio (95% CI)	2.64 (1.08, 6.44)	
	p-value	0.0329	
	Risk Difference (95% CI)	0.04 (0.01, 0.08)	
	p-value	0.0259	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Skin and subcutaneous tissue disorders, PT: Pruritus	Number of subjects with events, n/N (%)	21/243 (8.6)	31/238 (13.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.60 (0.34, 1.05)	
	p-value	0.0677	
	Relative Risk (95% CI)	0.66 (0.39, 1.12)	
	p-value	0.1251	
	Odds Ratio (95% CI)	0.63 (0.35, 1.13)	
	p-value	0.1240	
	Risk Difference (95% CI)	-0.04 (-0.10, 0.01)	
	p-value	0.1214	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Skin and subcutaneous tissue disorders, PT: Rash	Number of subjects with events, n/N (%)	58/243 (23.9)	53/238 (22.3)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	10.71 (5.06, NE)	NE (2.43, NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.97 (0.67, 1.41)	
	p-value	0.8787	
	Relative Risk (95% CI)	1.07 (0.77, 1.49)	
	p-value	0.6774	
	Odds Ratio (95% CI)	1.09 (0.72, 1.67)	
	p-value	0.6773	
	Risk Difference (95% CI)	0.02 (-0.06, 0.09)	
	p-value	0.6771	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Skin and subcutaneous tissue disorders, PT: Rash maculo-papular	Number of subjects with events, n/N (%)	16/243 (6.6)	15/238 (6.3)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.98 (0.49, 1.99)	
	p-value	0.9650	
	Relative Risk (95% CI)	1.04 (0.53, 2.06)	
	p-value	0.8999	
	Odds Ratio (95% CI)	1.05 (0.51, 2.17)	
	p-value	0.8999	
	Risk Difference (95% CI)	0.00 (-0.04, 0.05)	
	p-value	0.8998	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Vascular disorders	Number of subjects with events, n/N (%)	38/243 (15.6)	28/238 (11.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.32 (0.81, 2.15)	
	p-value	0.2646	
	Relative Risk (95% CI)	1.33 (0.84, 2.09)	
	p-value	0.2195	
	Odds Ratio (95% CI)	1.39 (0.82, 2.35)	
	p-value	0.2184	
	Risk Difference (95% CI)	0.04 (-0.02, 0.10)	
	p-value	0.2158	

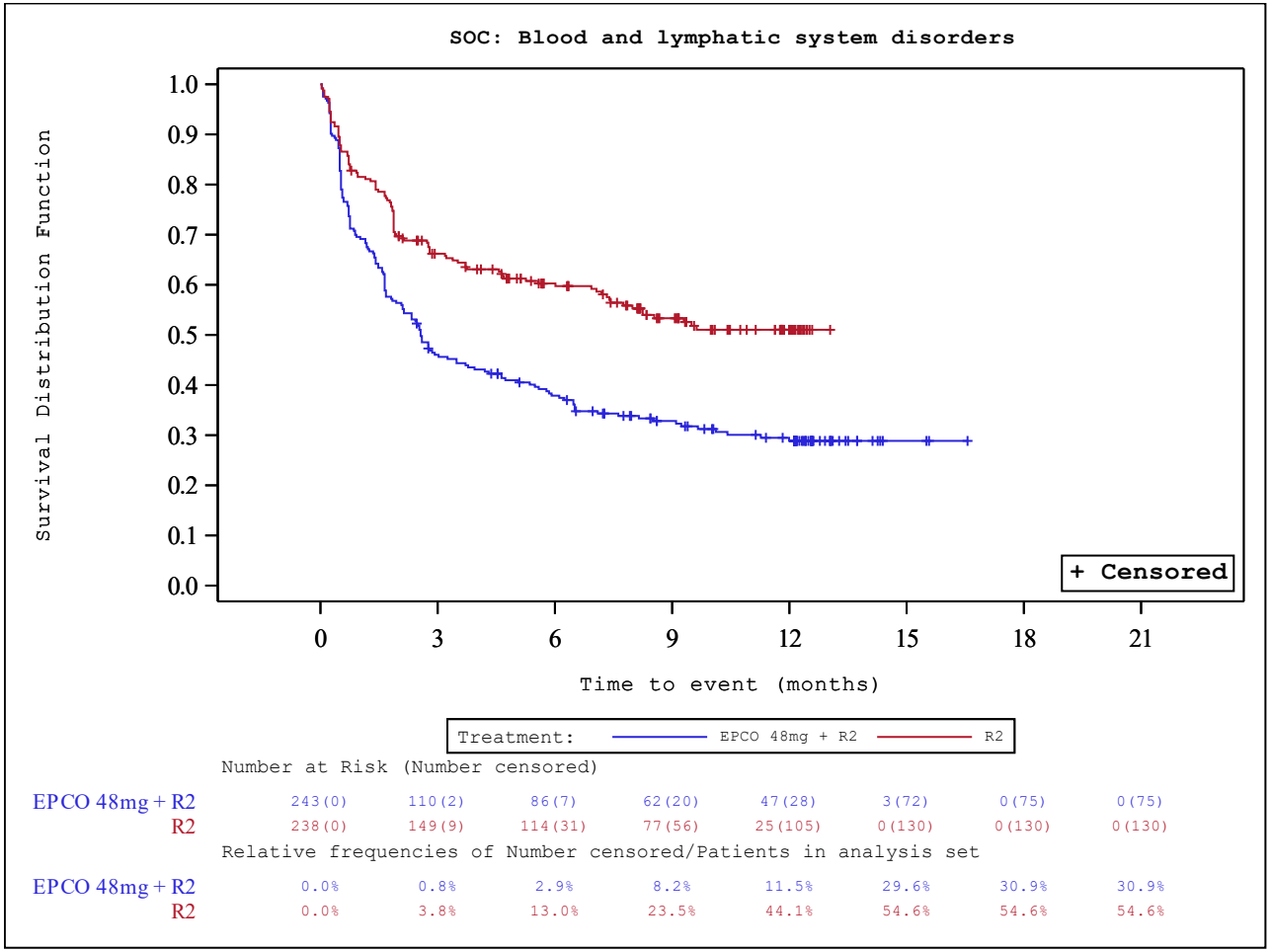
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.1 Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Vascular disorders, PT: Hypotension	Number of subjects with events, n/N (%)	14/243 (5.8)	3/238 (1.3)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	4.53 (1.30, 15.78)	
	p-value	0.0091	
	Relative Risk (95% CI)	4.57 (1.33, 15.70)	
	p-value	0.0158	
	Odds Ratio (95% CI)	4.79 (1.36, 16.89)	
	p-value	0.0148	
	Risk Difference (95% CI)	0.05 (0.01, 0.08)	
	p-value	0.0067	

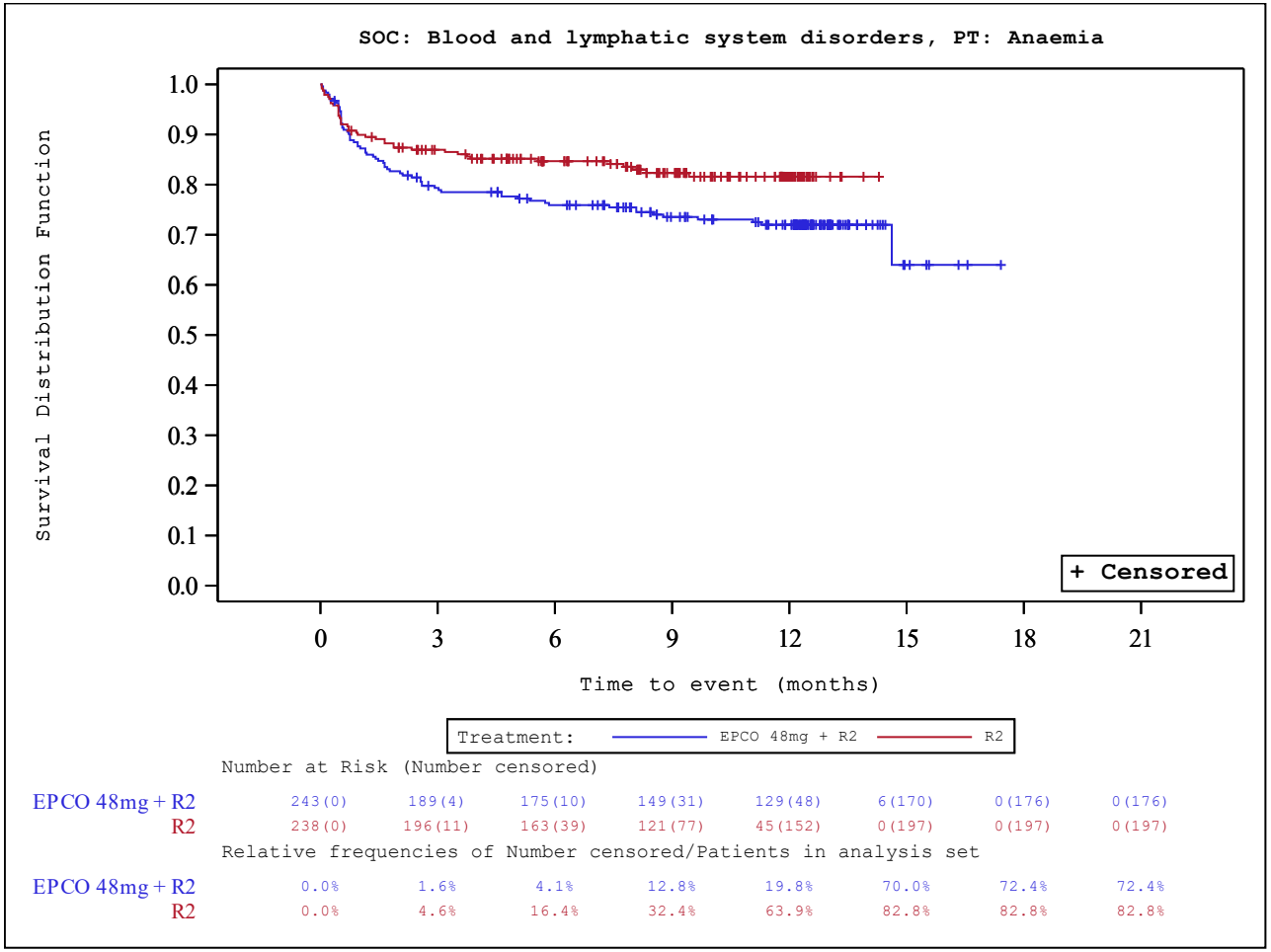
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



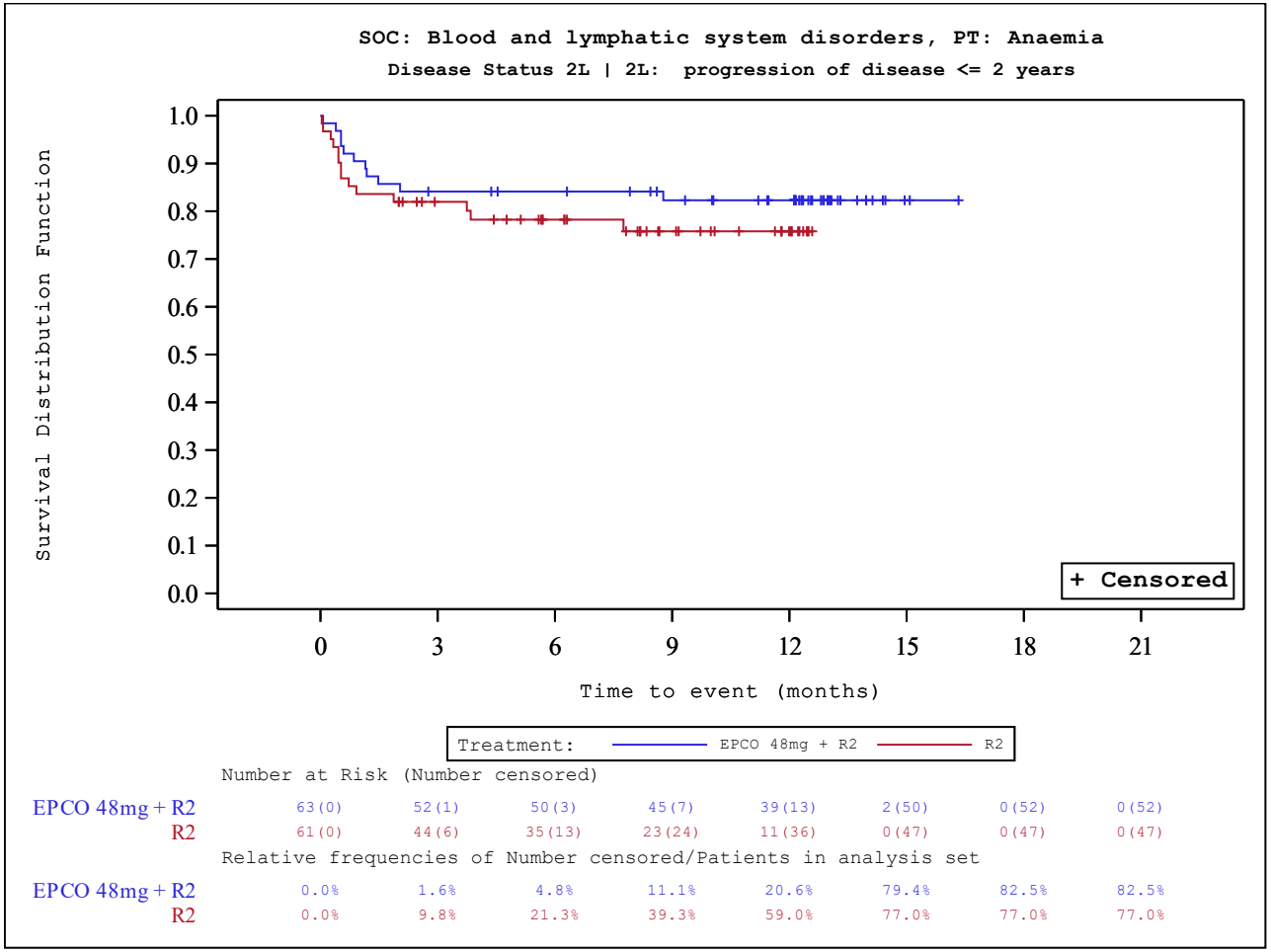
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



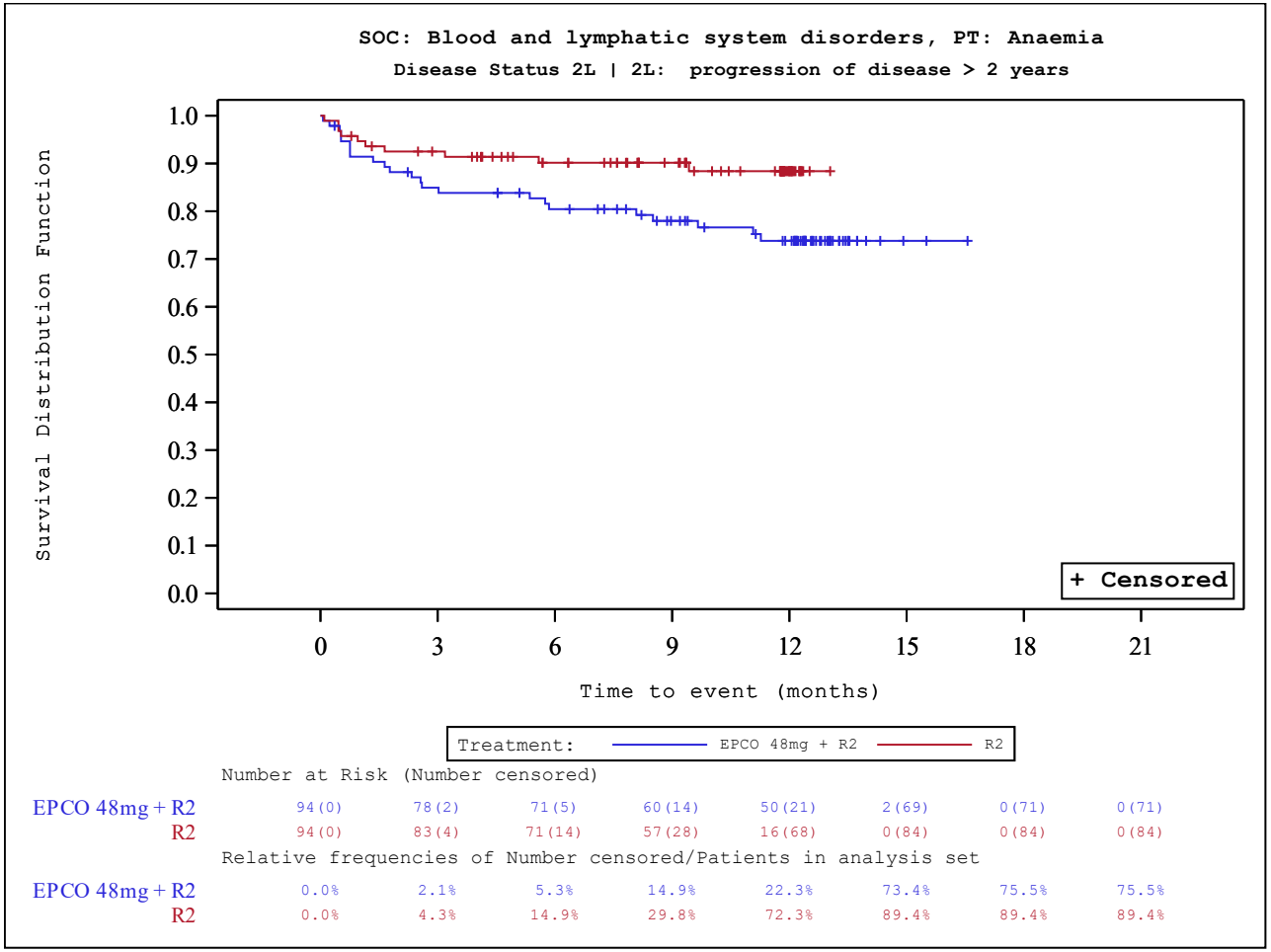
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



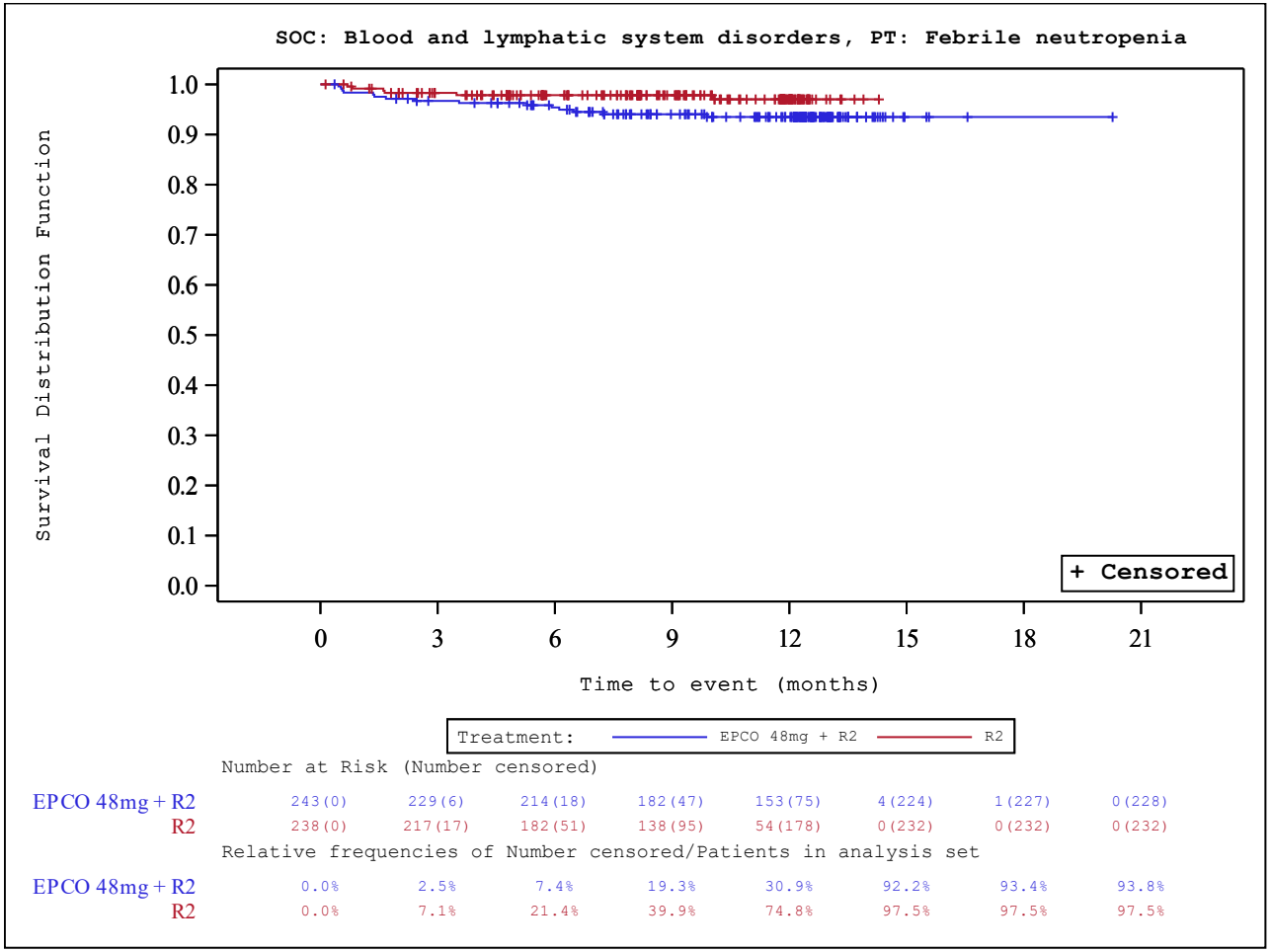
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



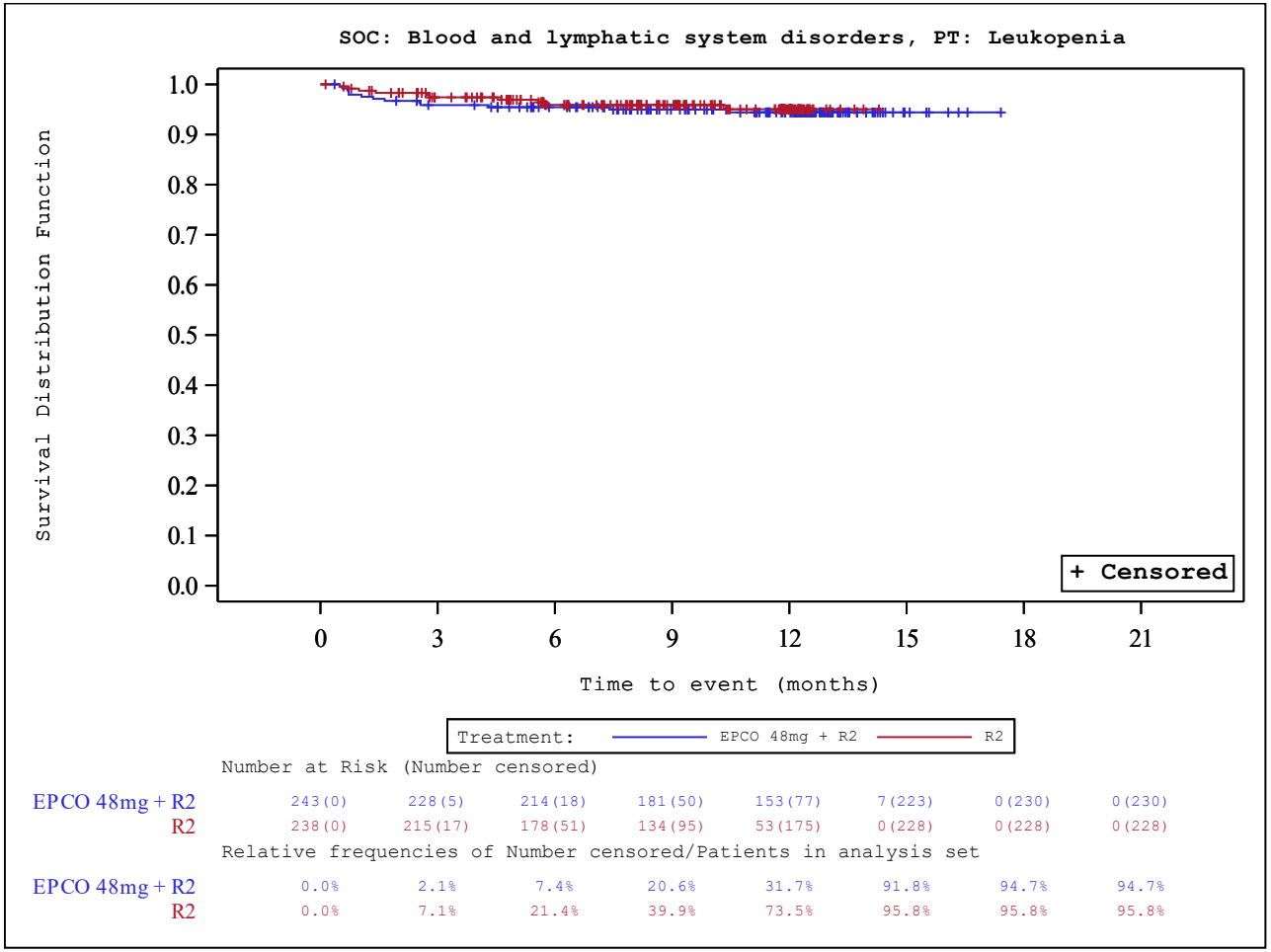
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



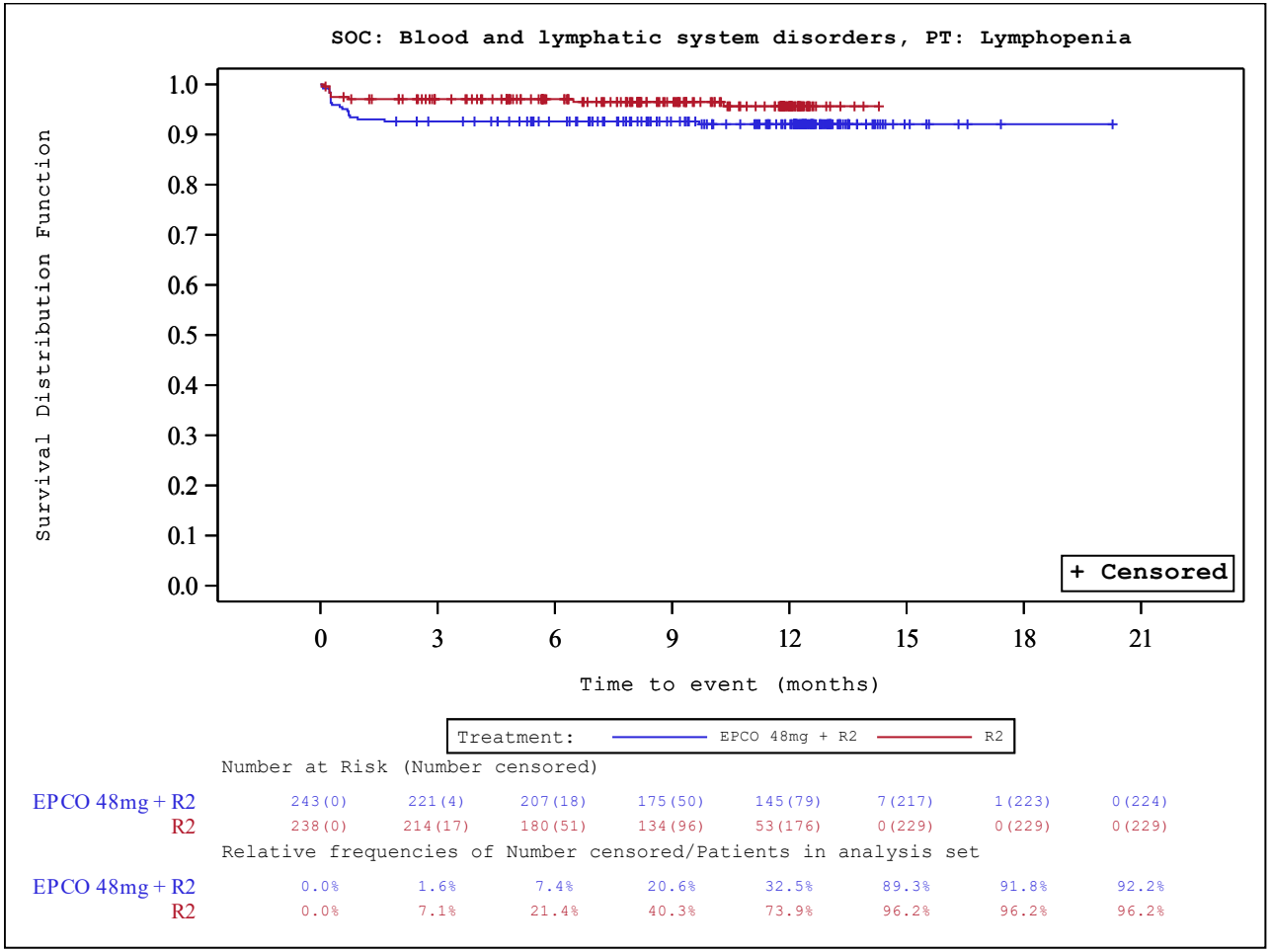
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



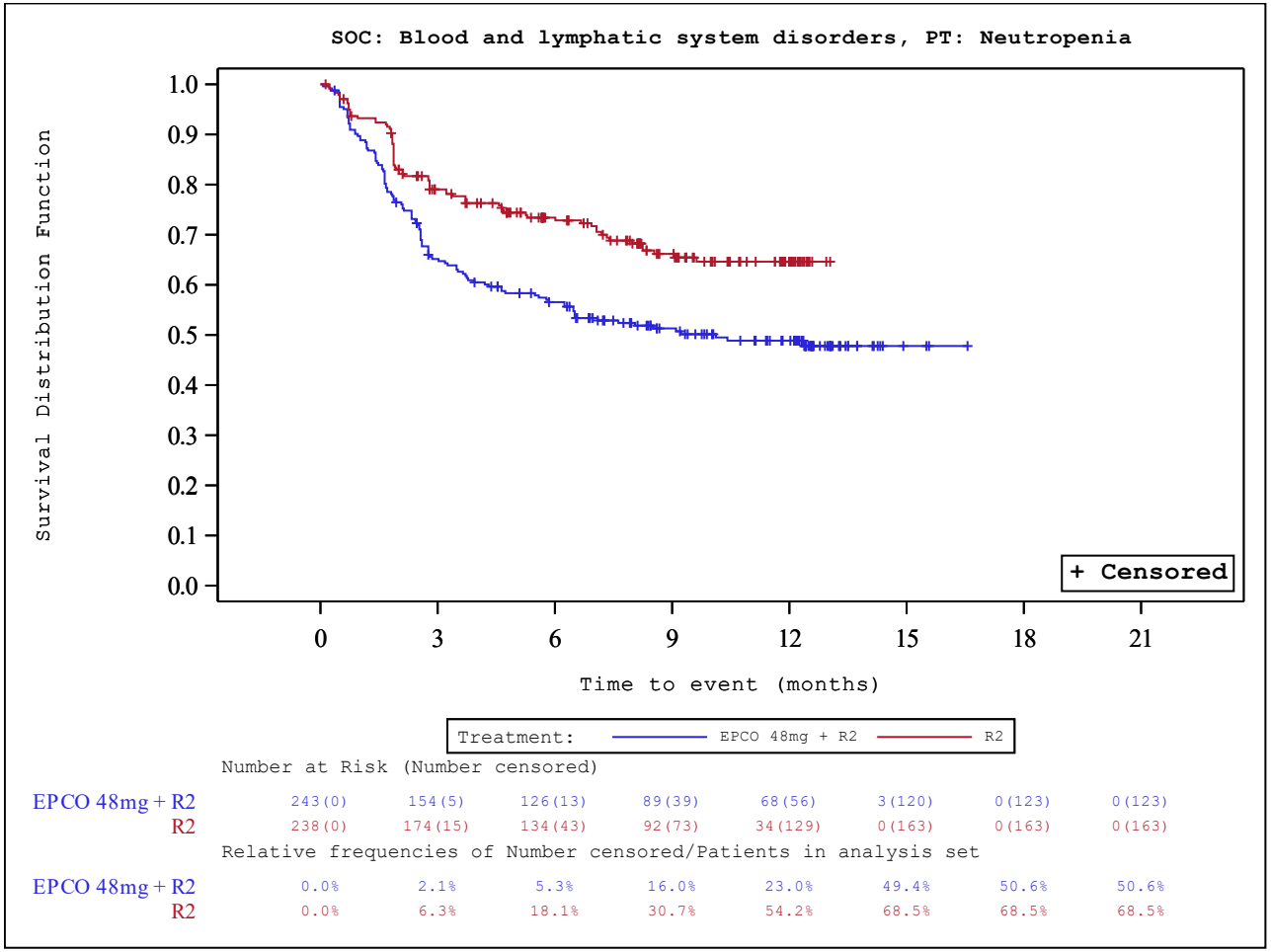
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



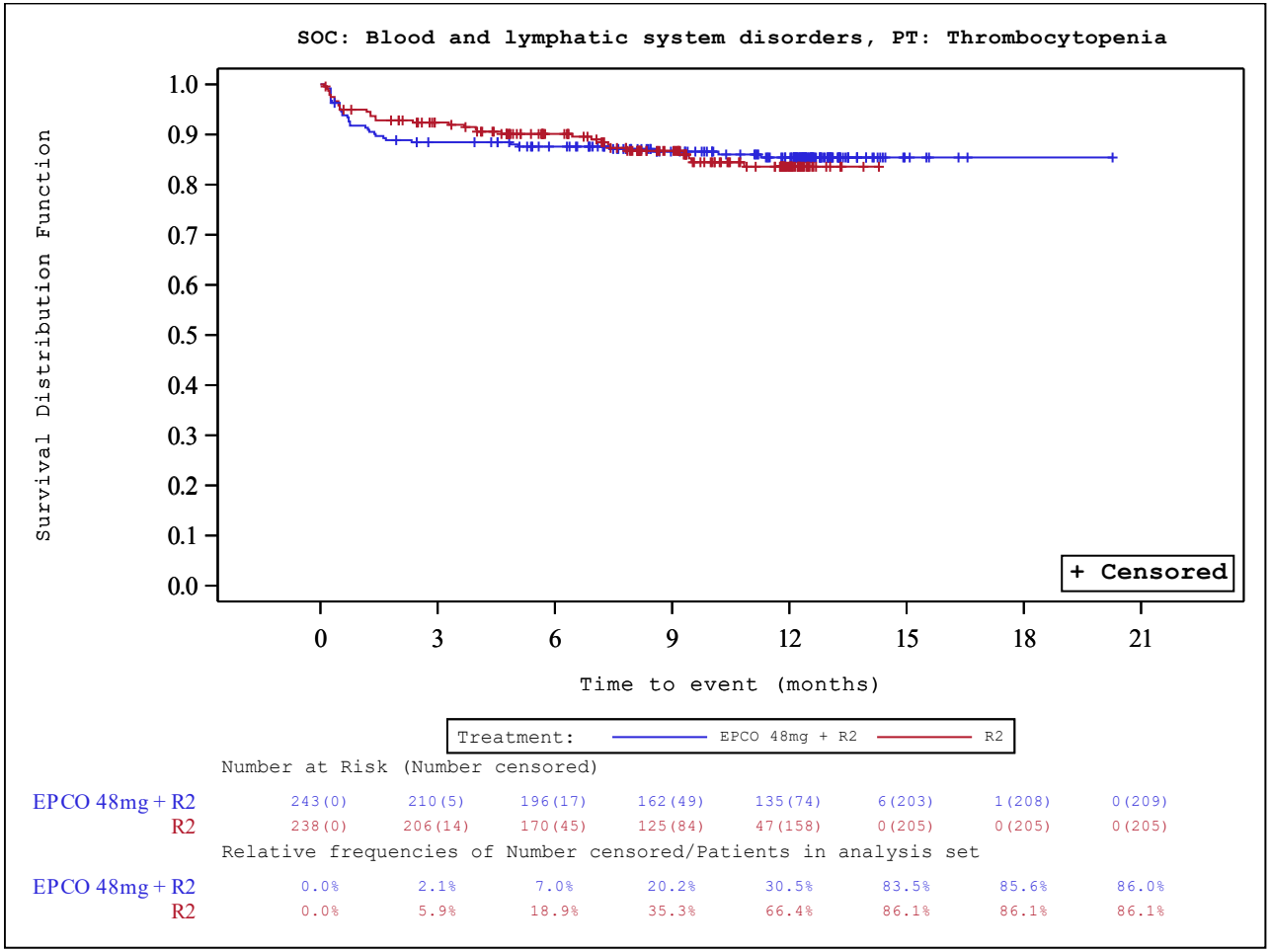
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



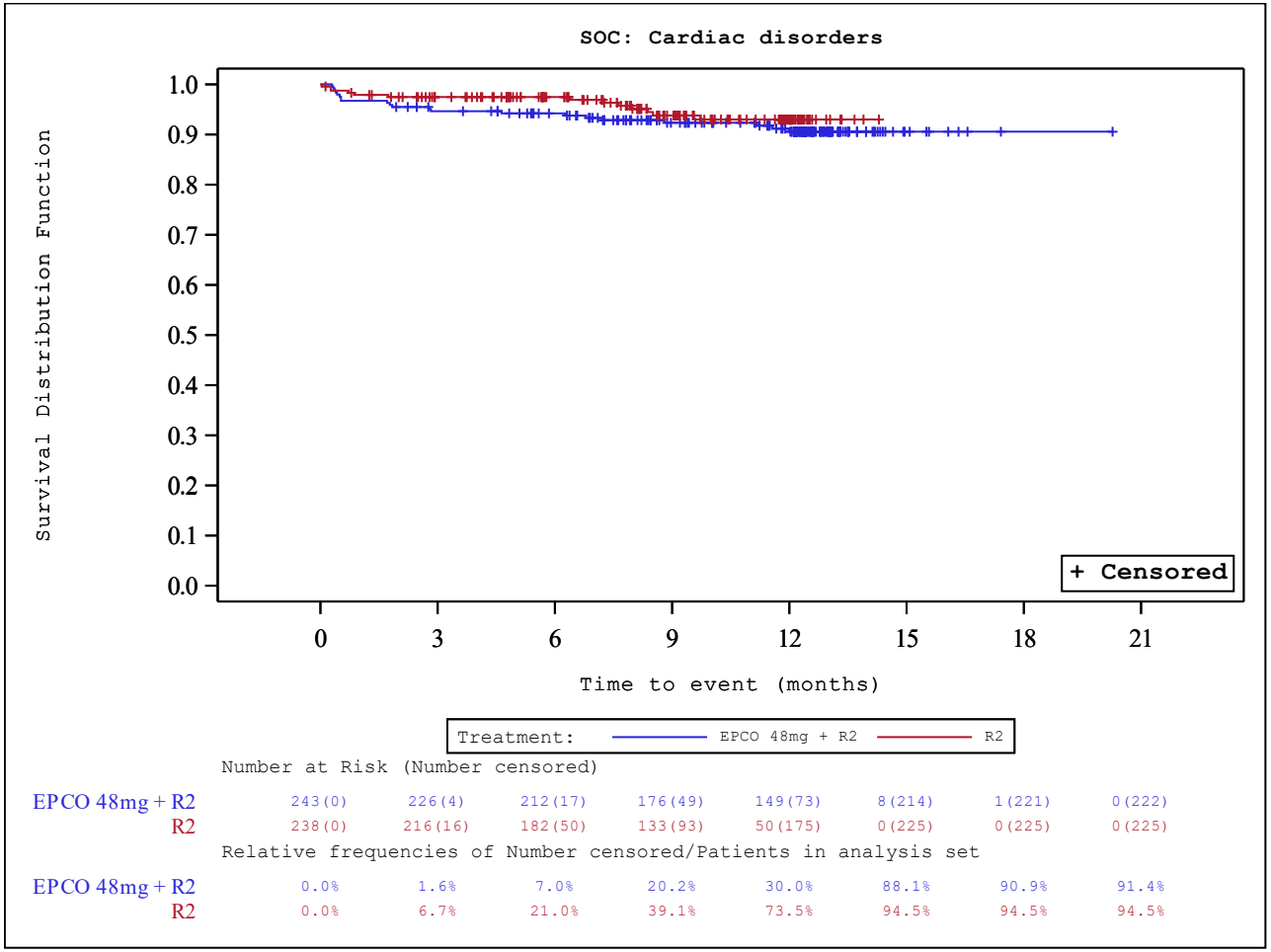
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



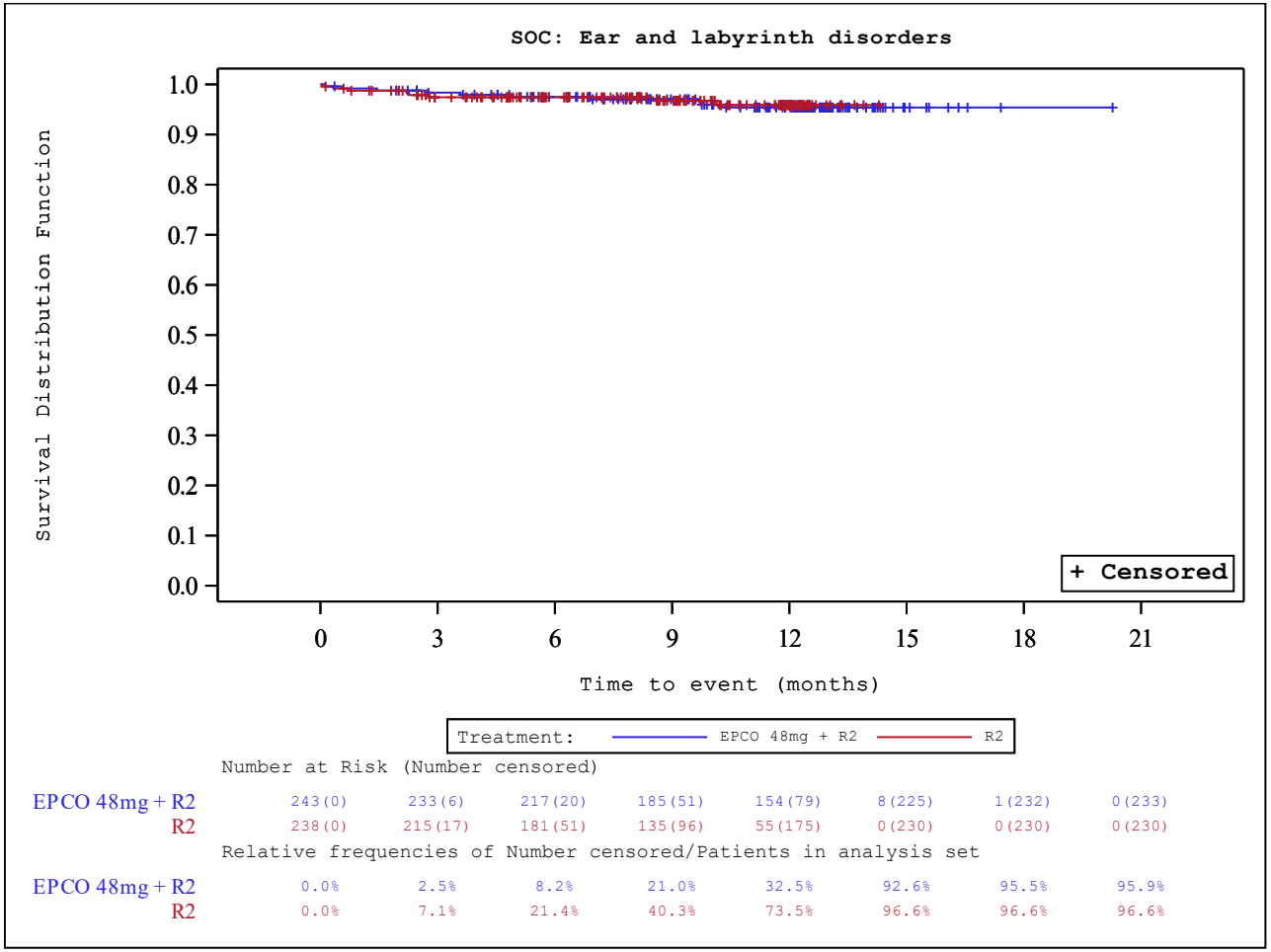
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



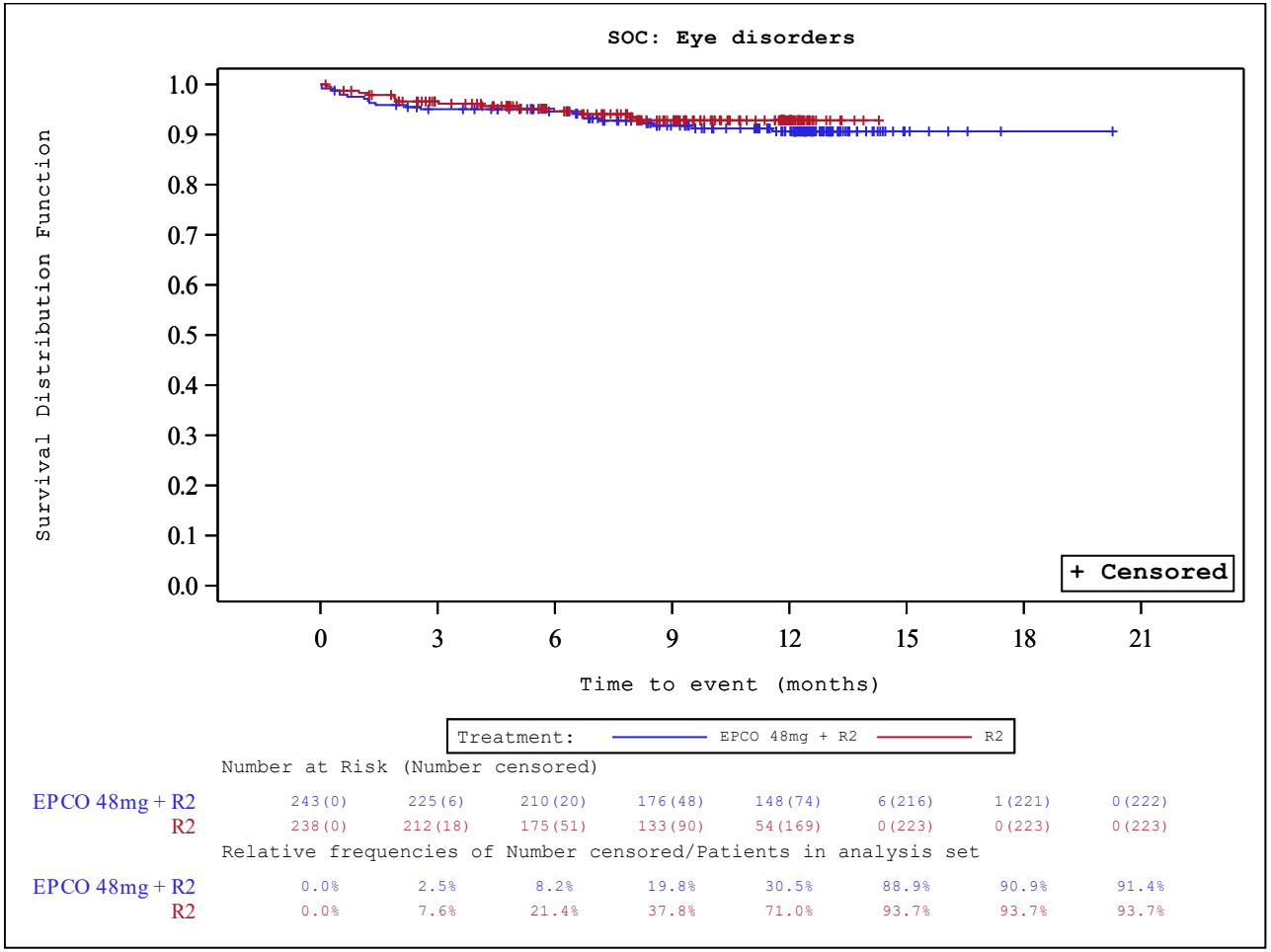
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



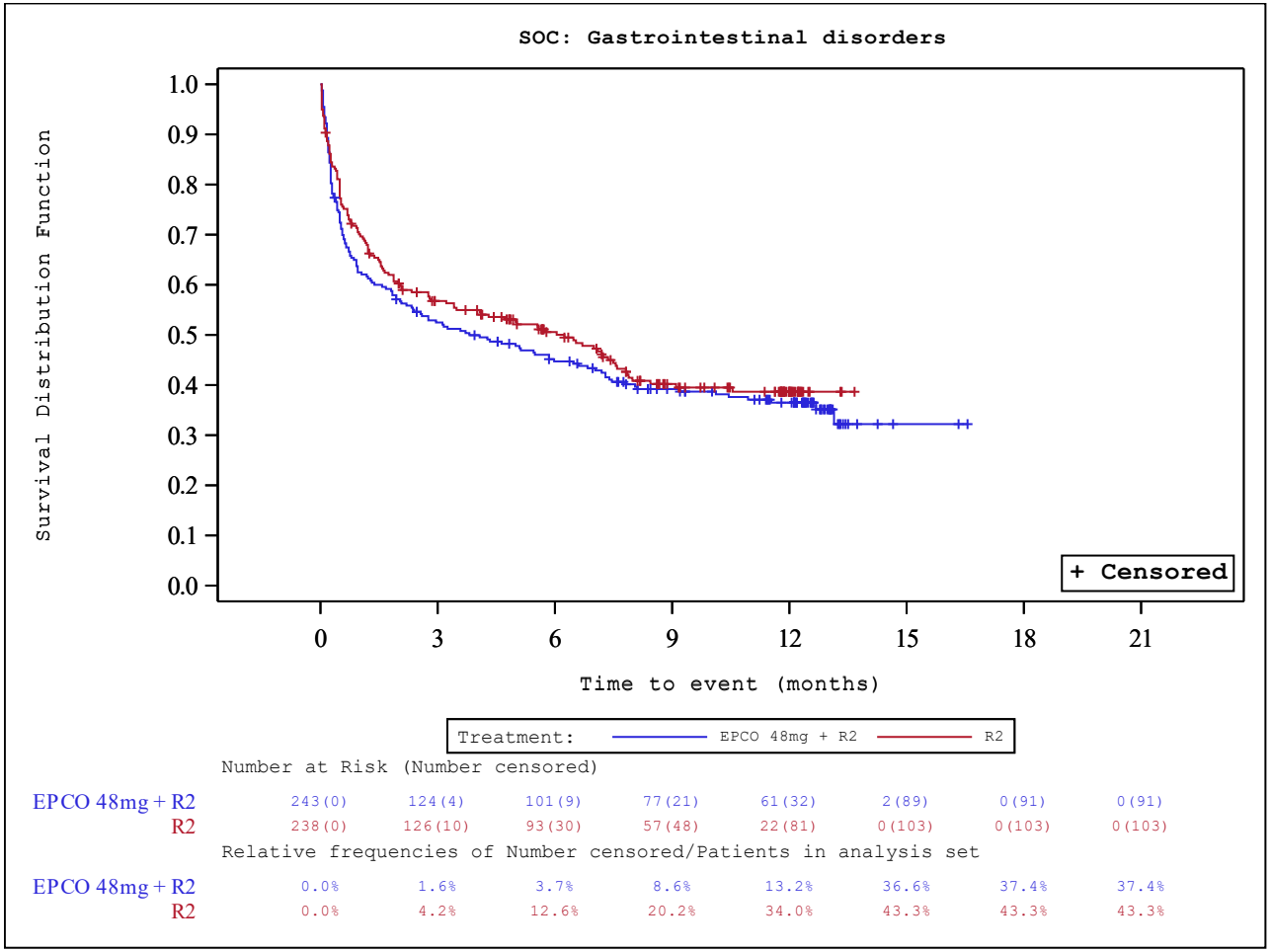
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



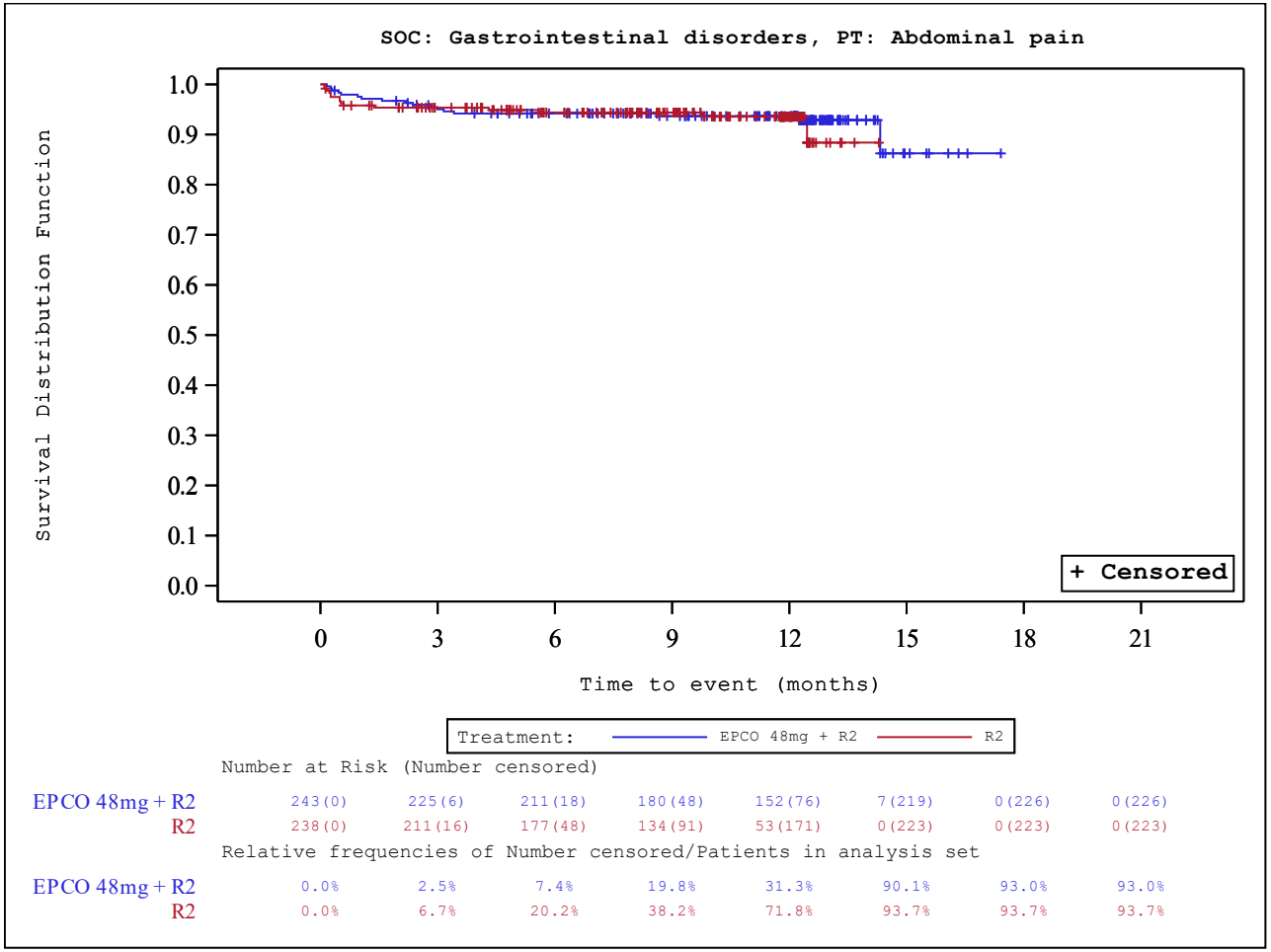
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



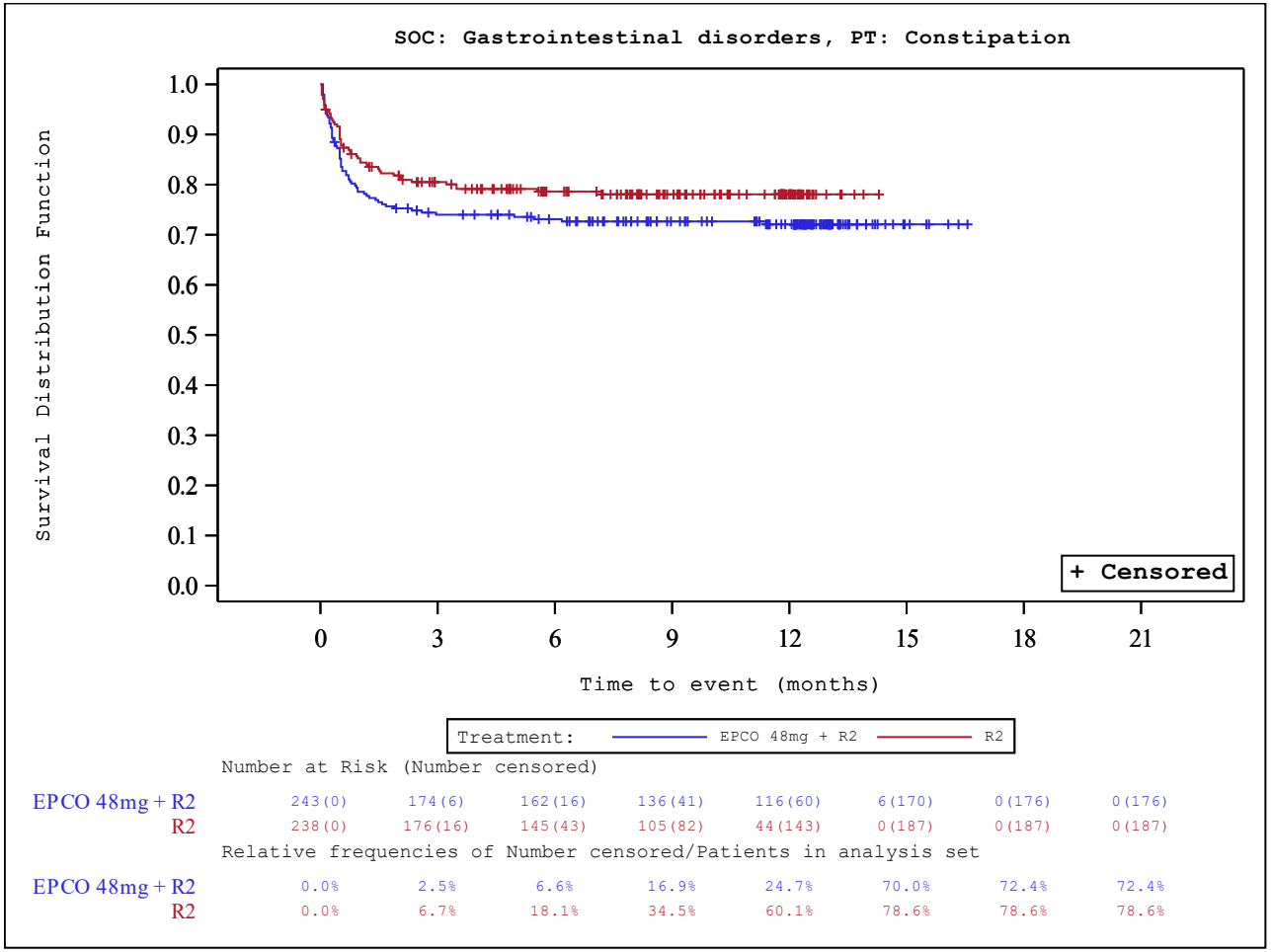
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



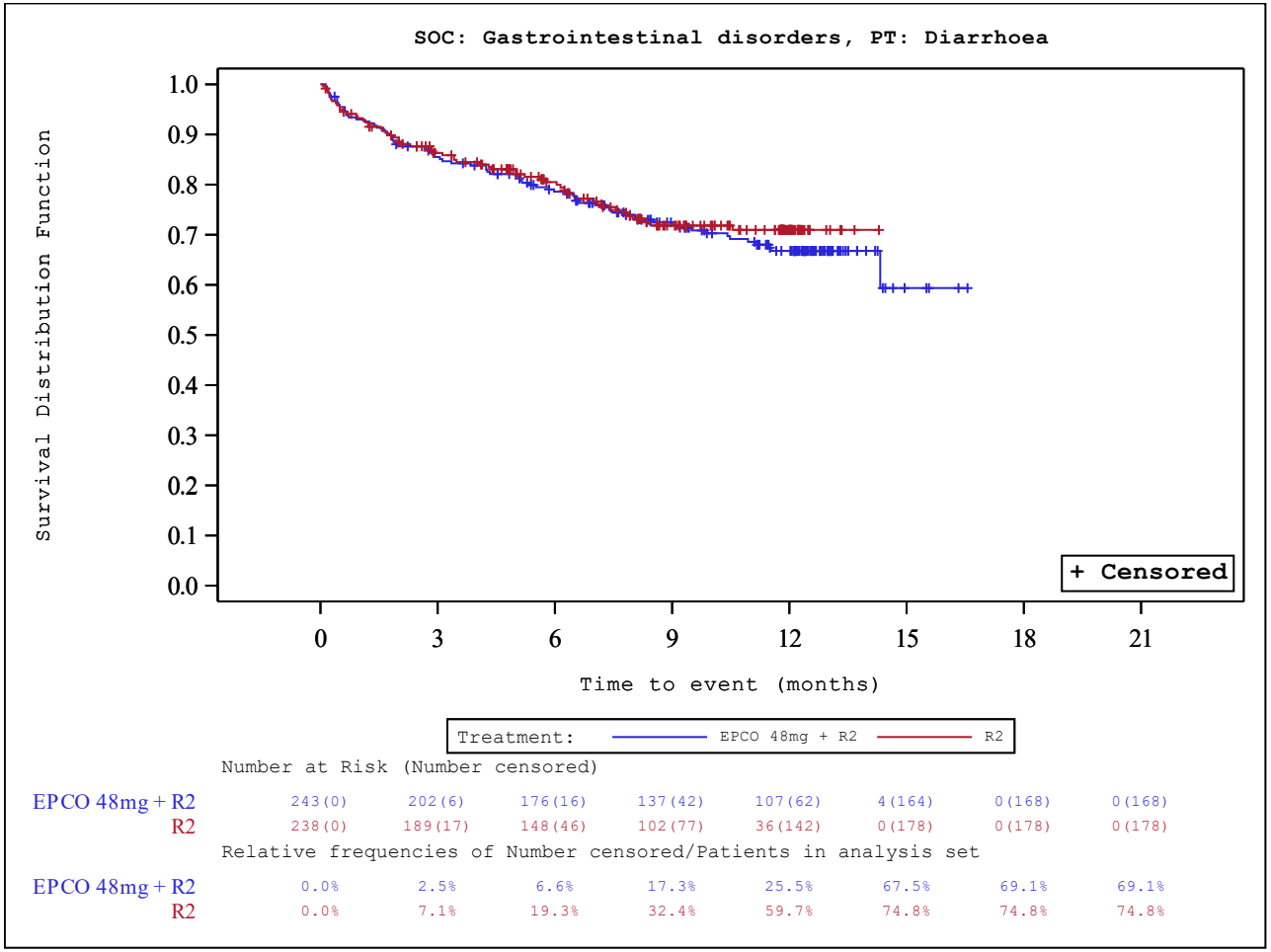
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



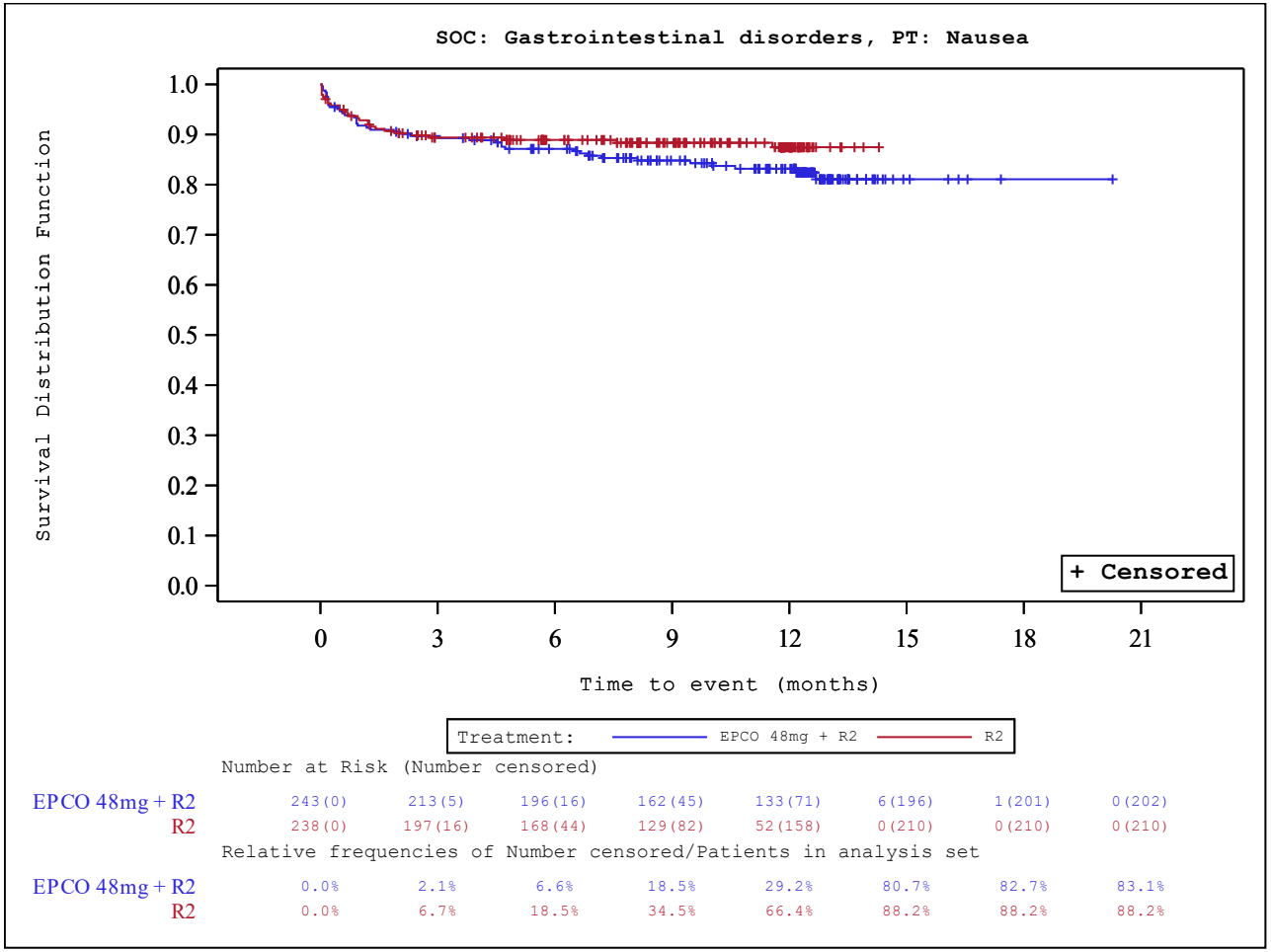
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



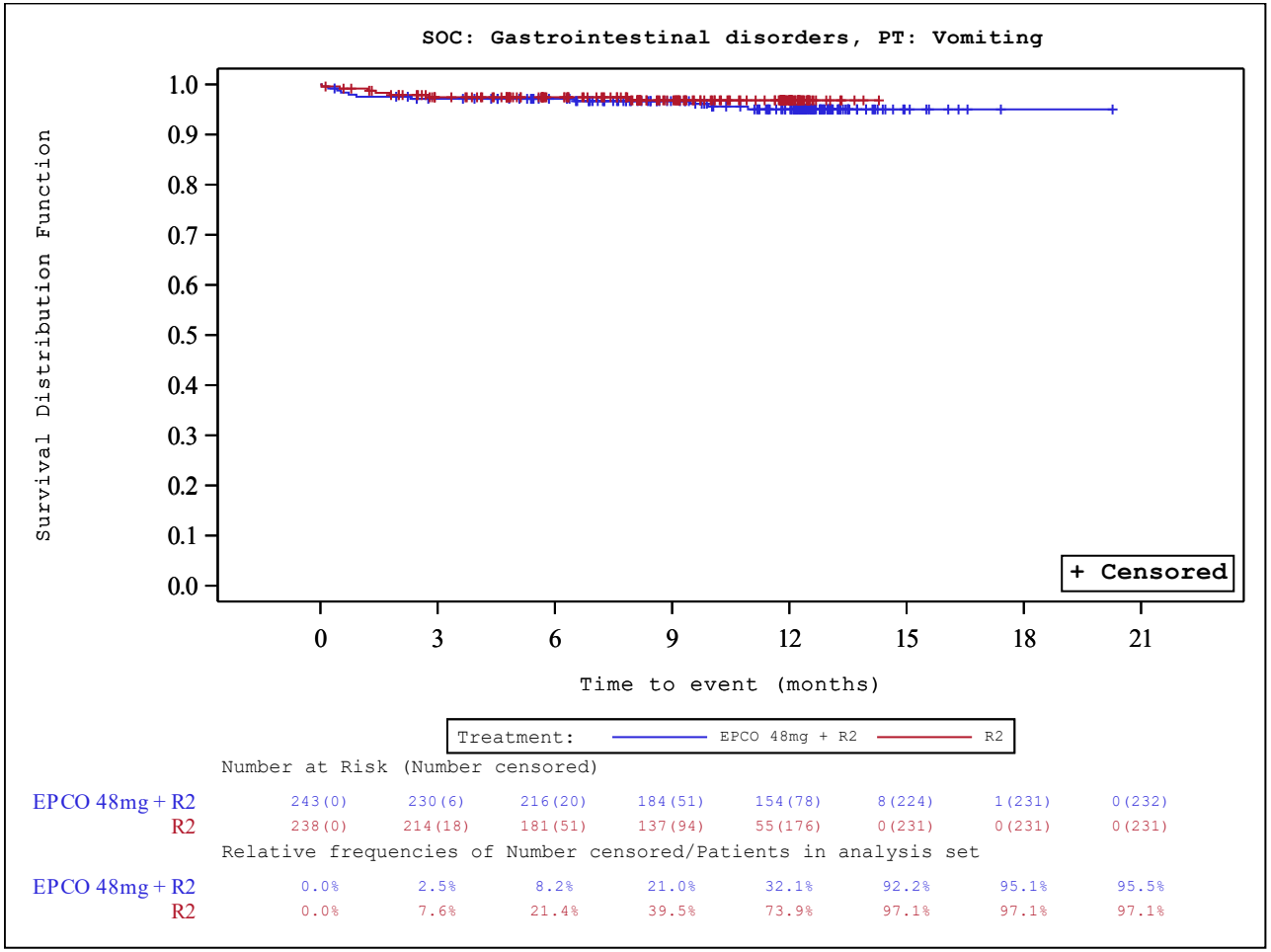
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



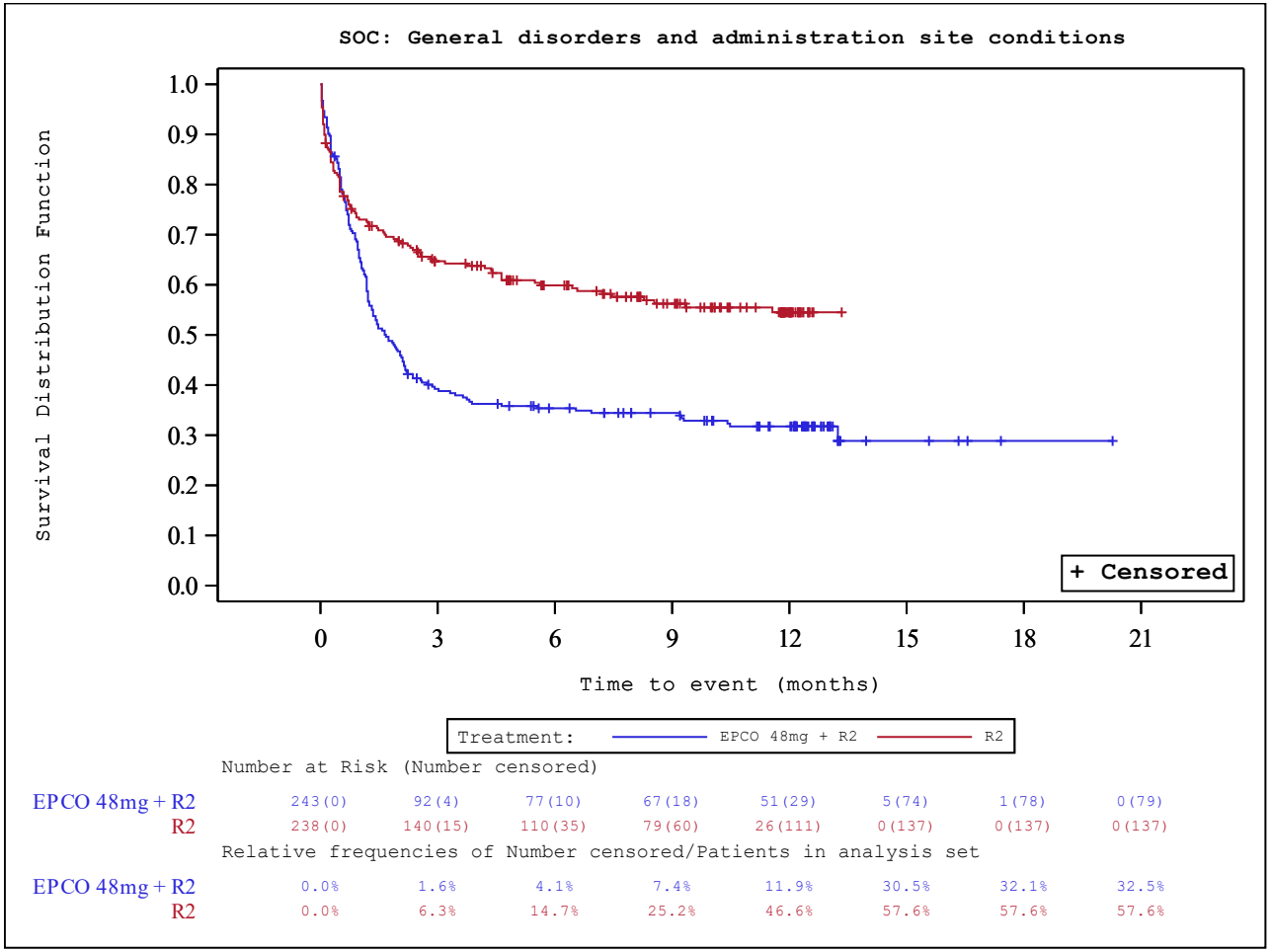
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



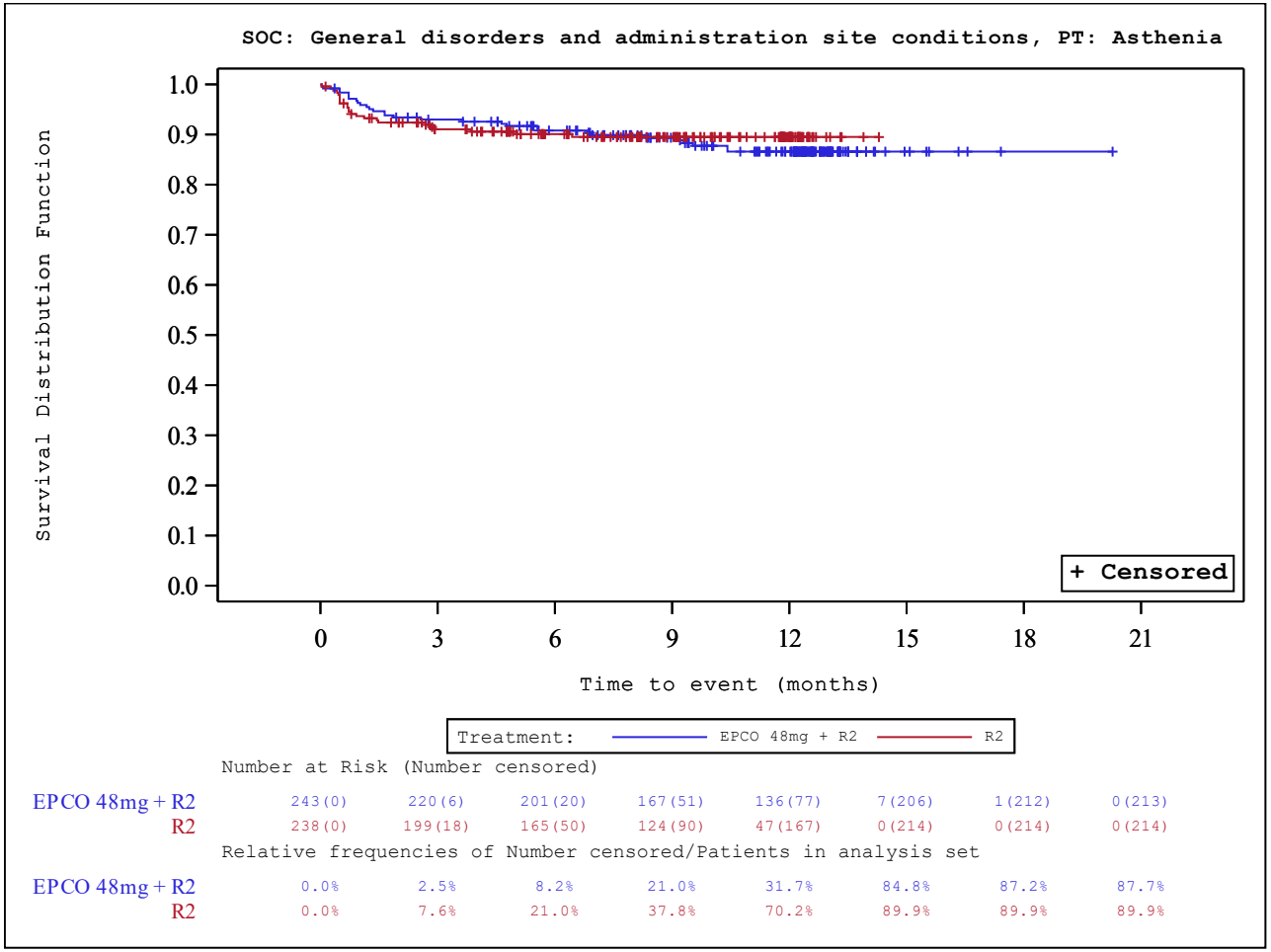
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



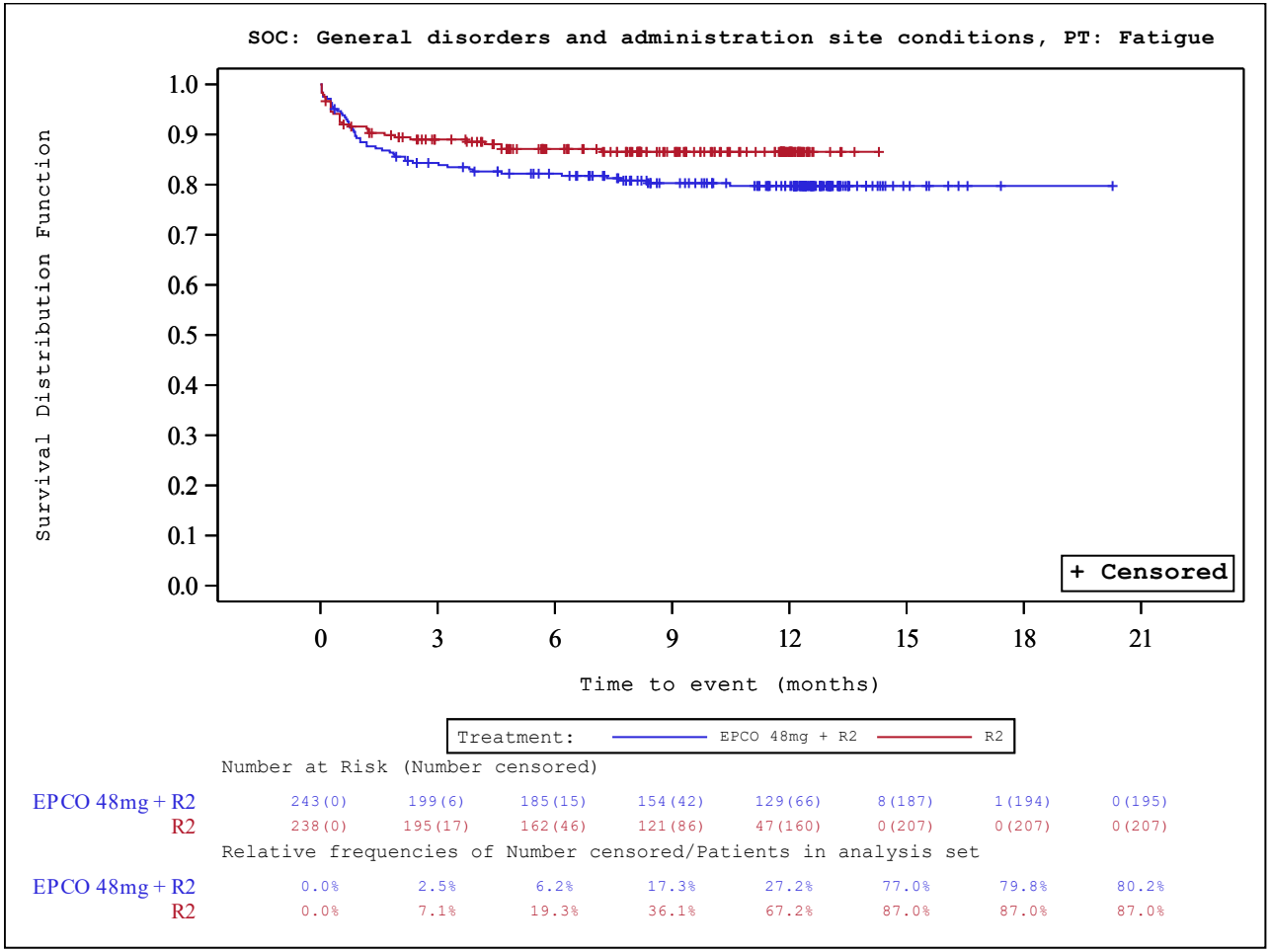
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



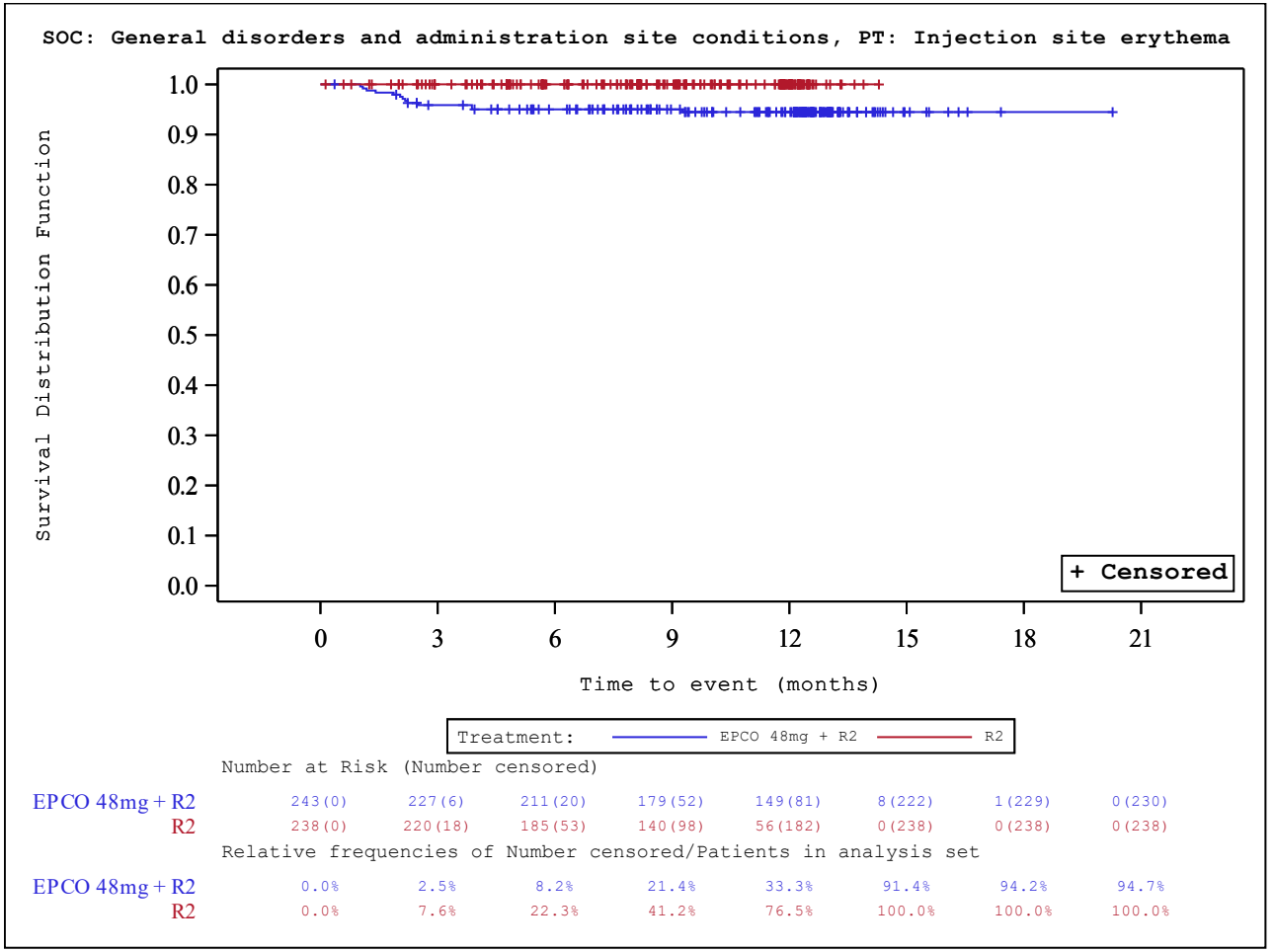
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



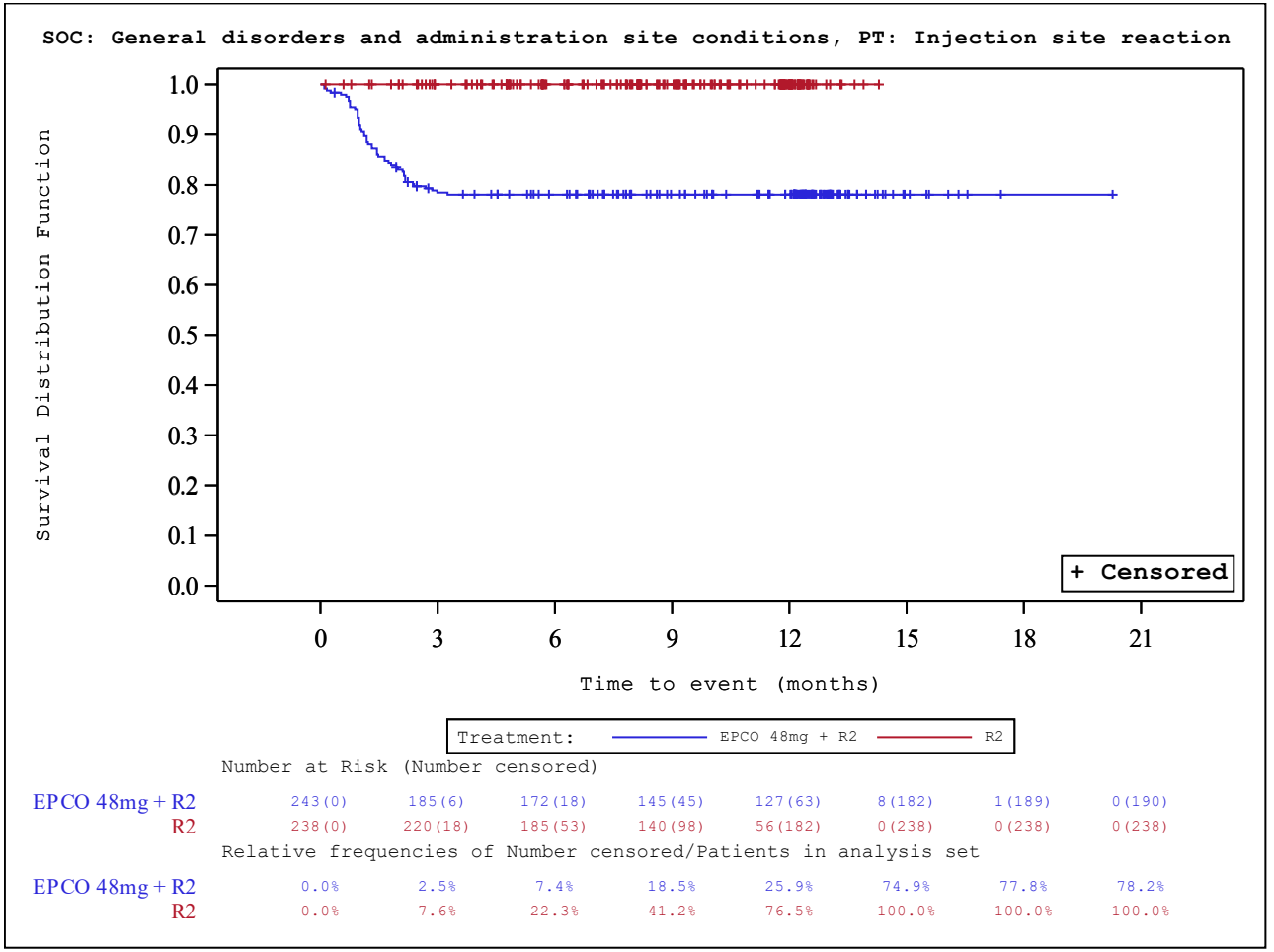
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



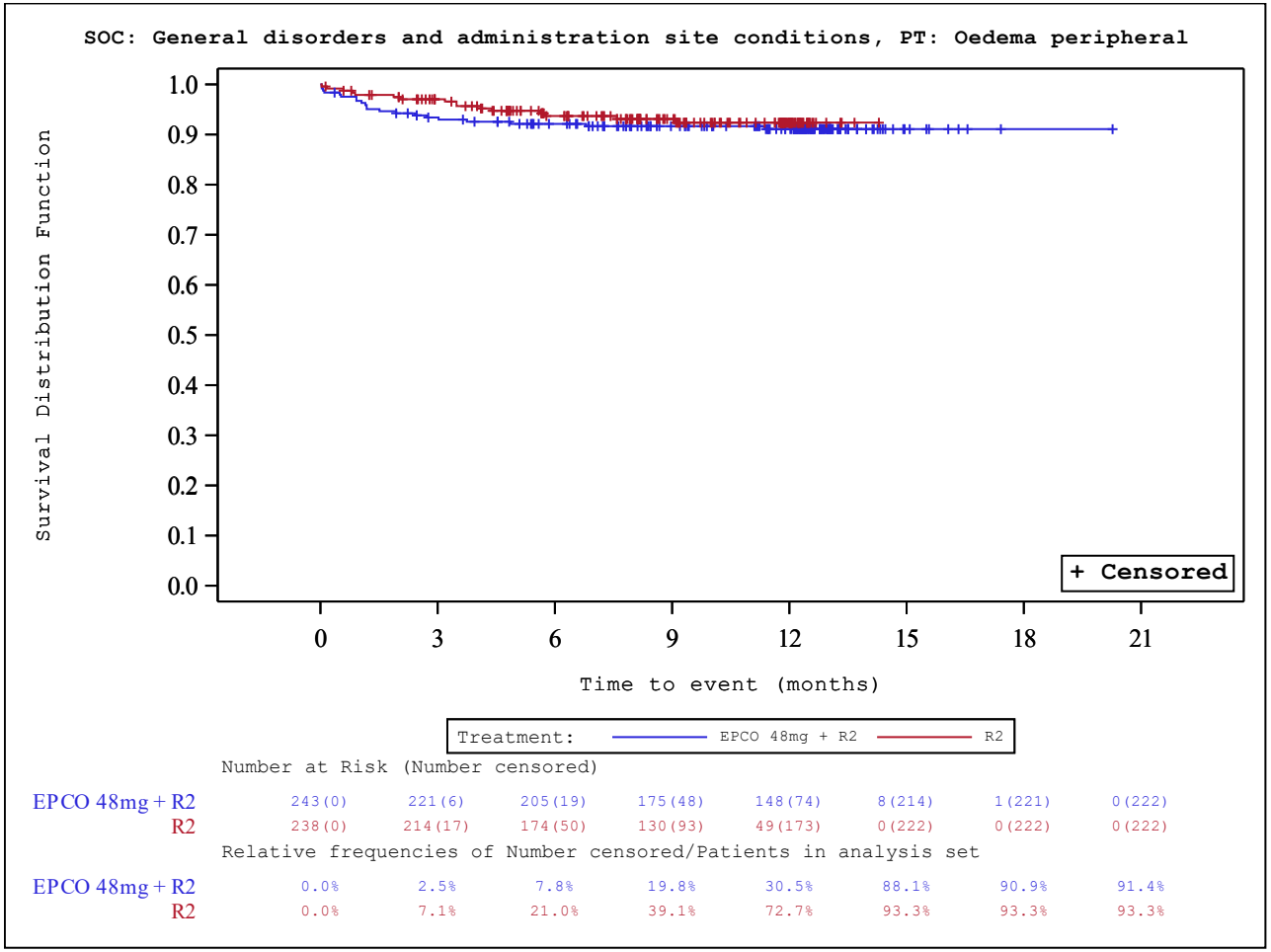
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



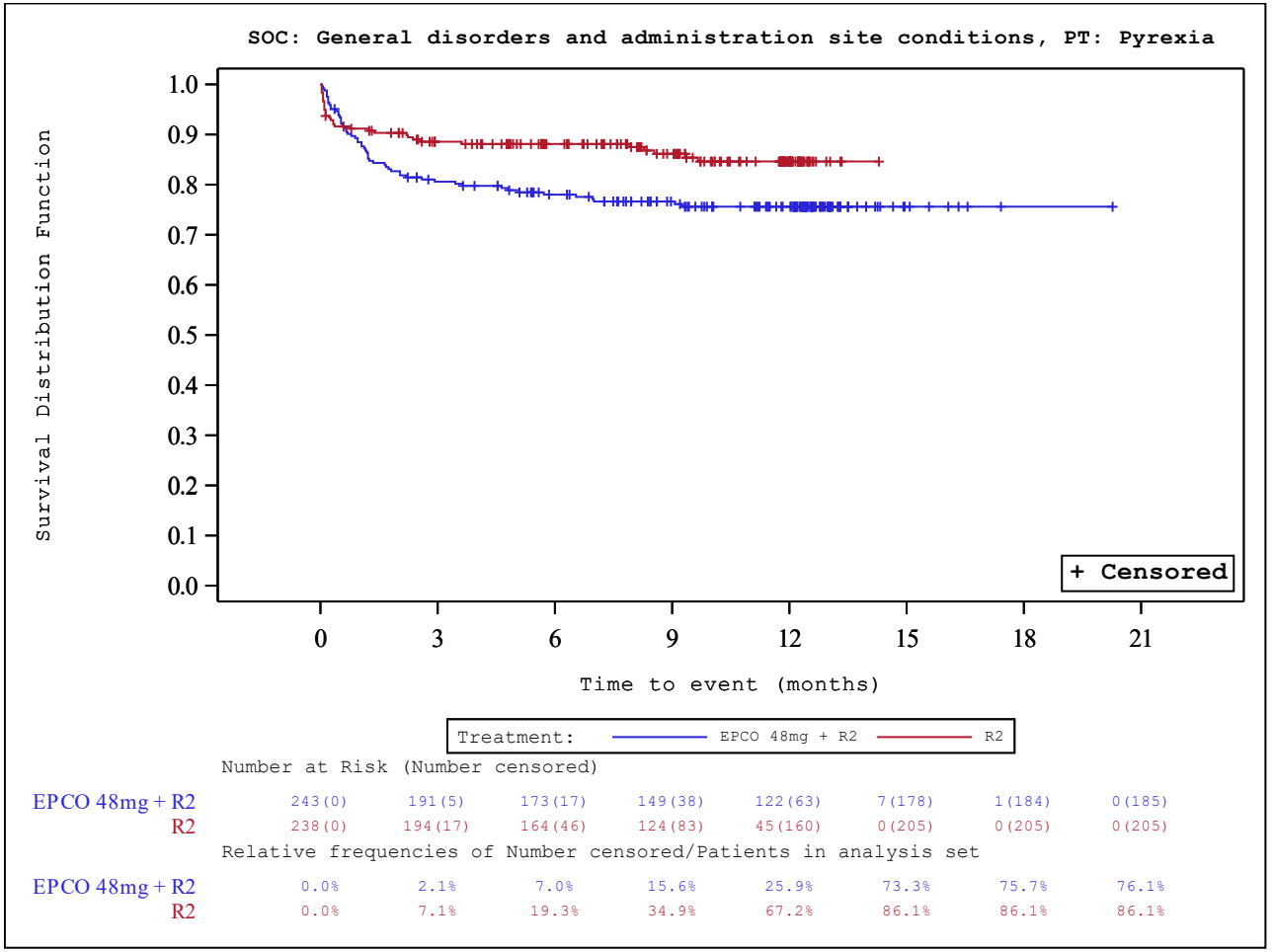
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



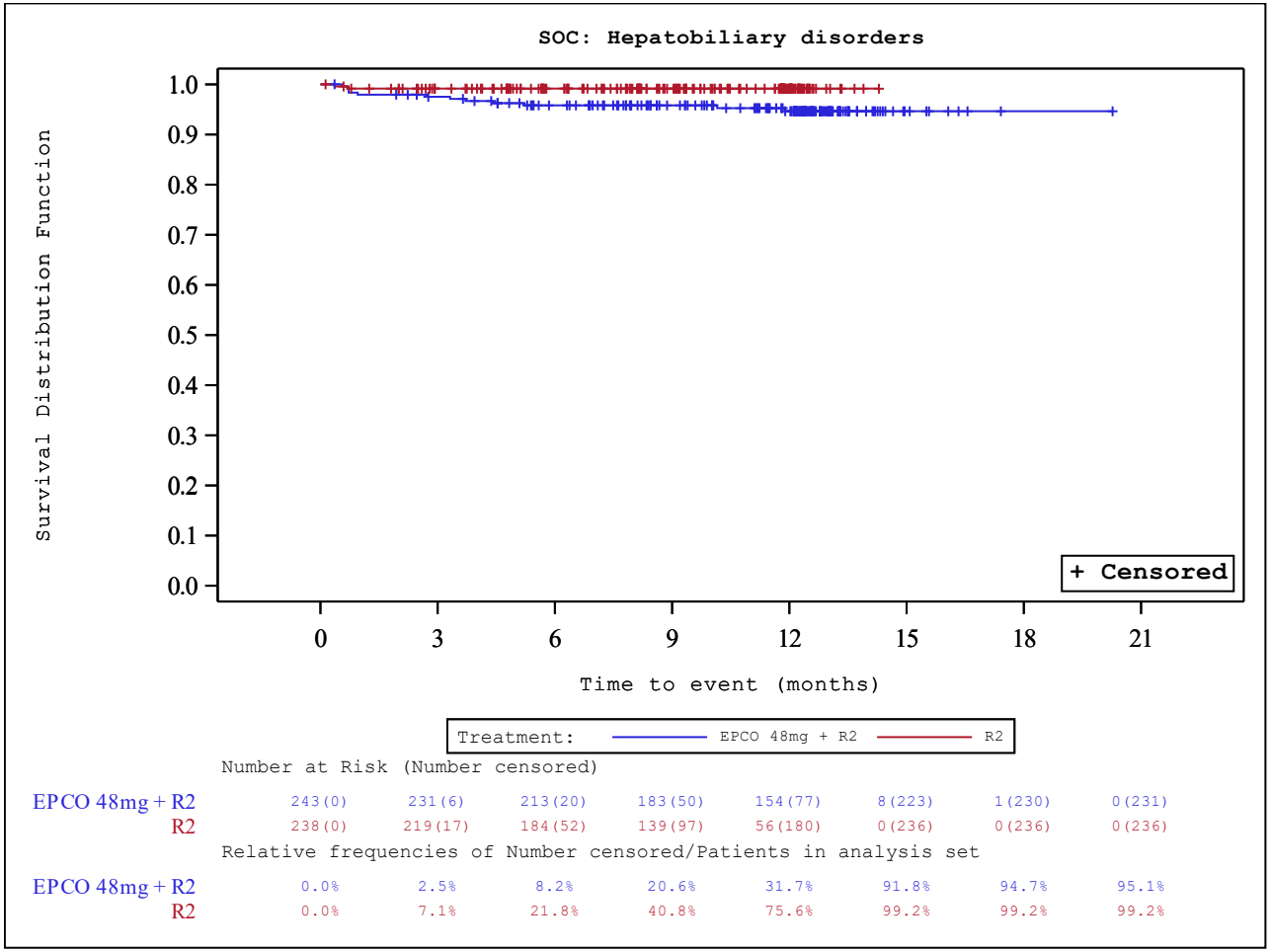
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



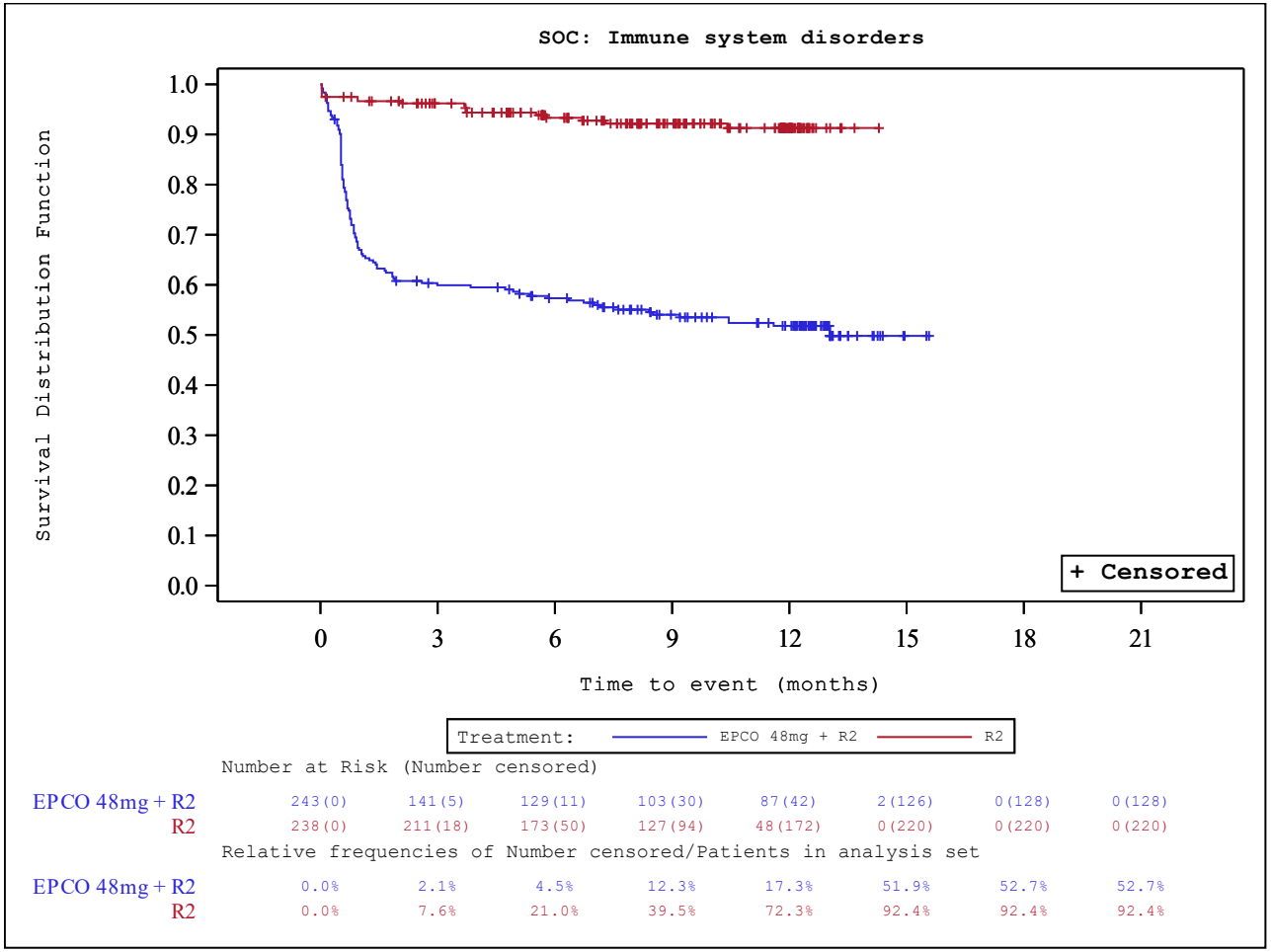
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



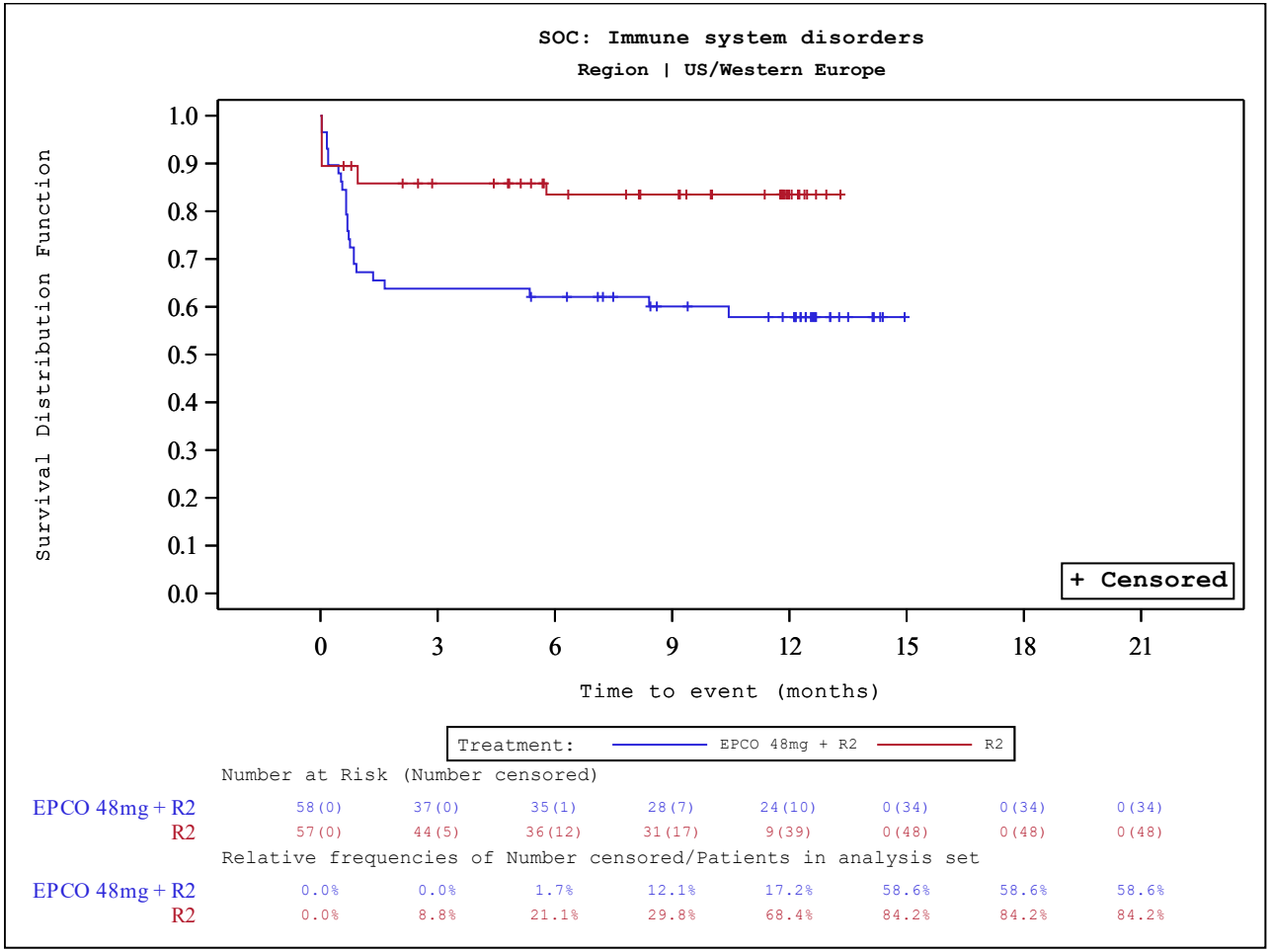
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



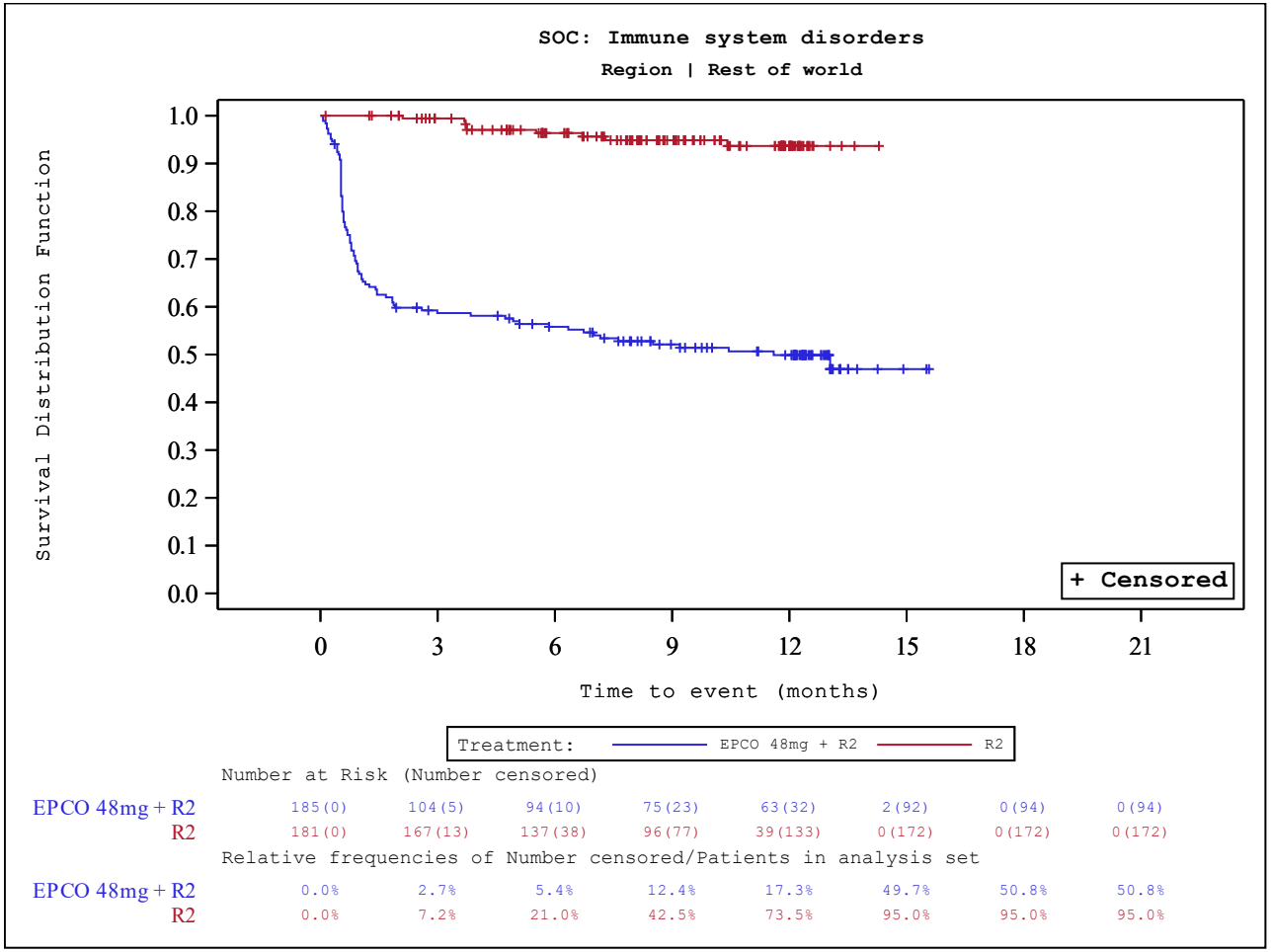
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



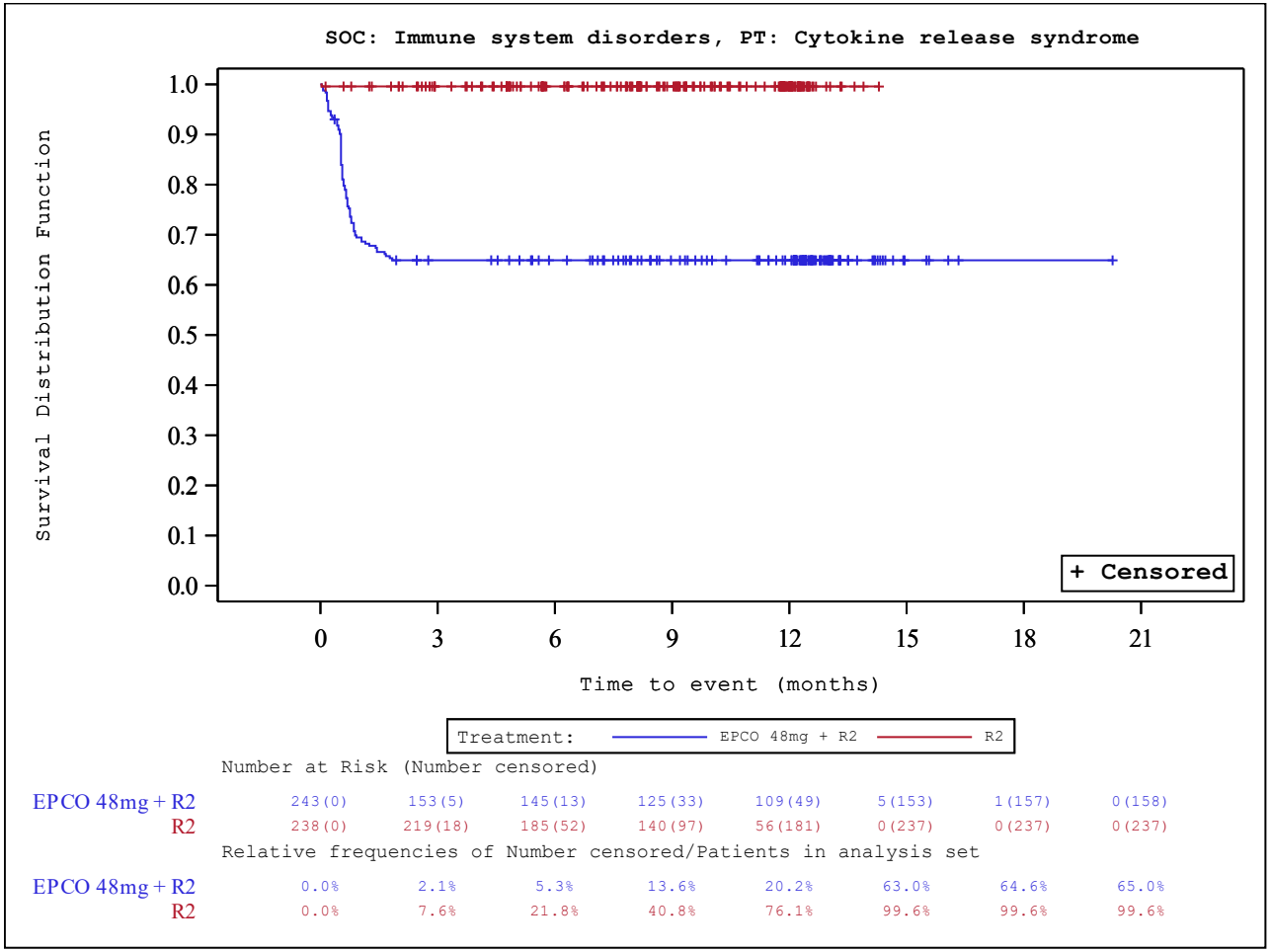
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



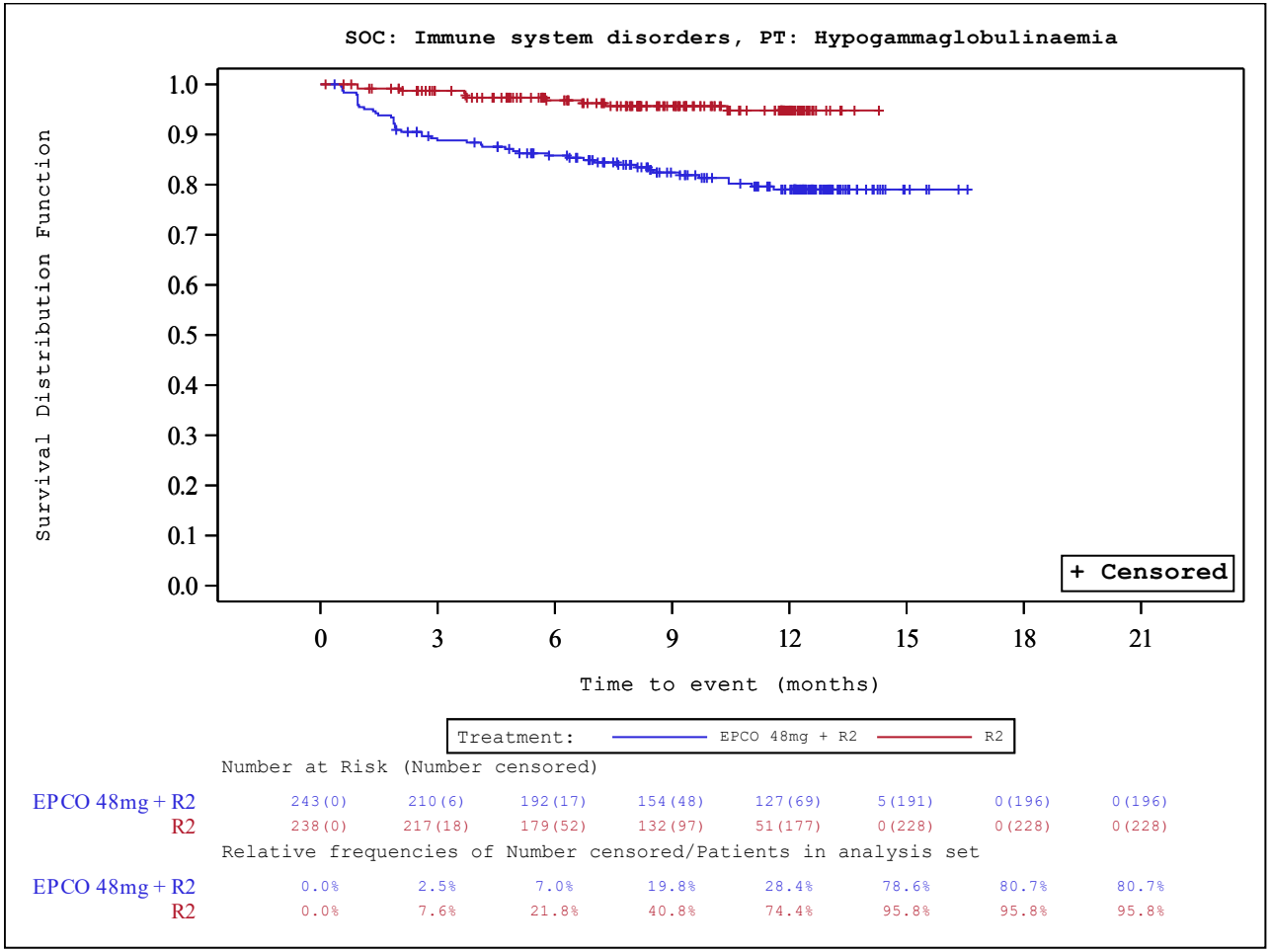
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



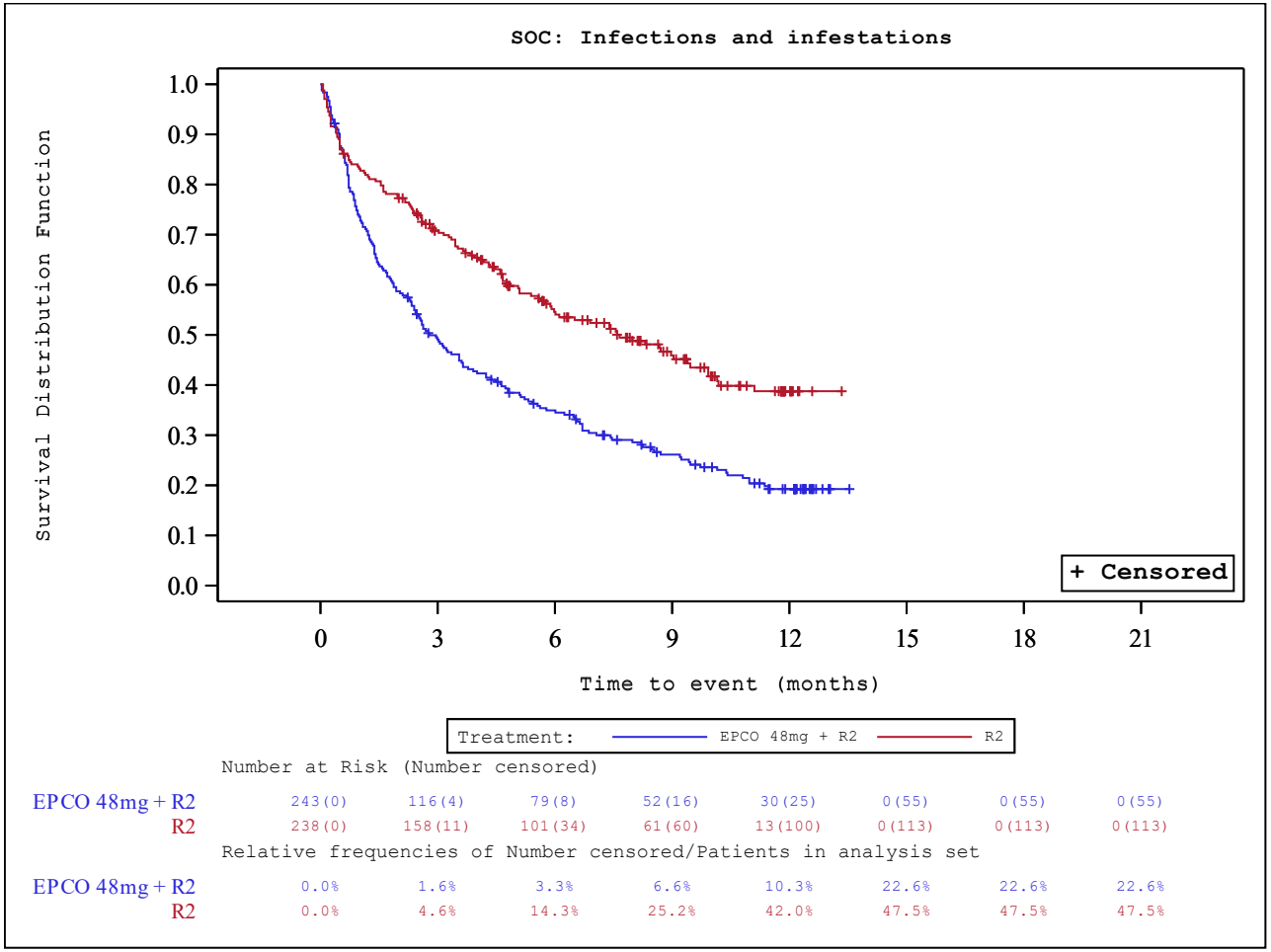
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



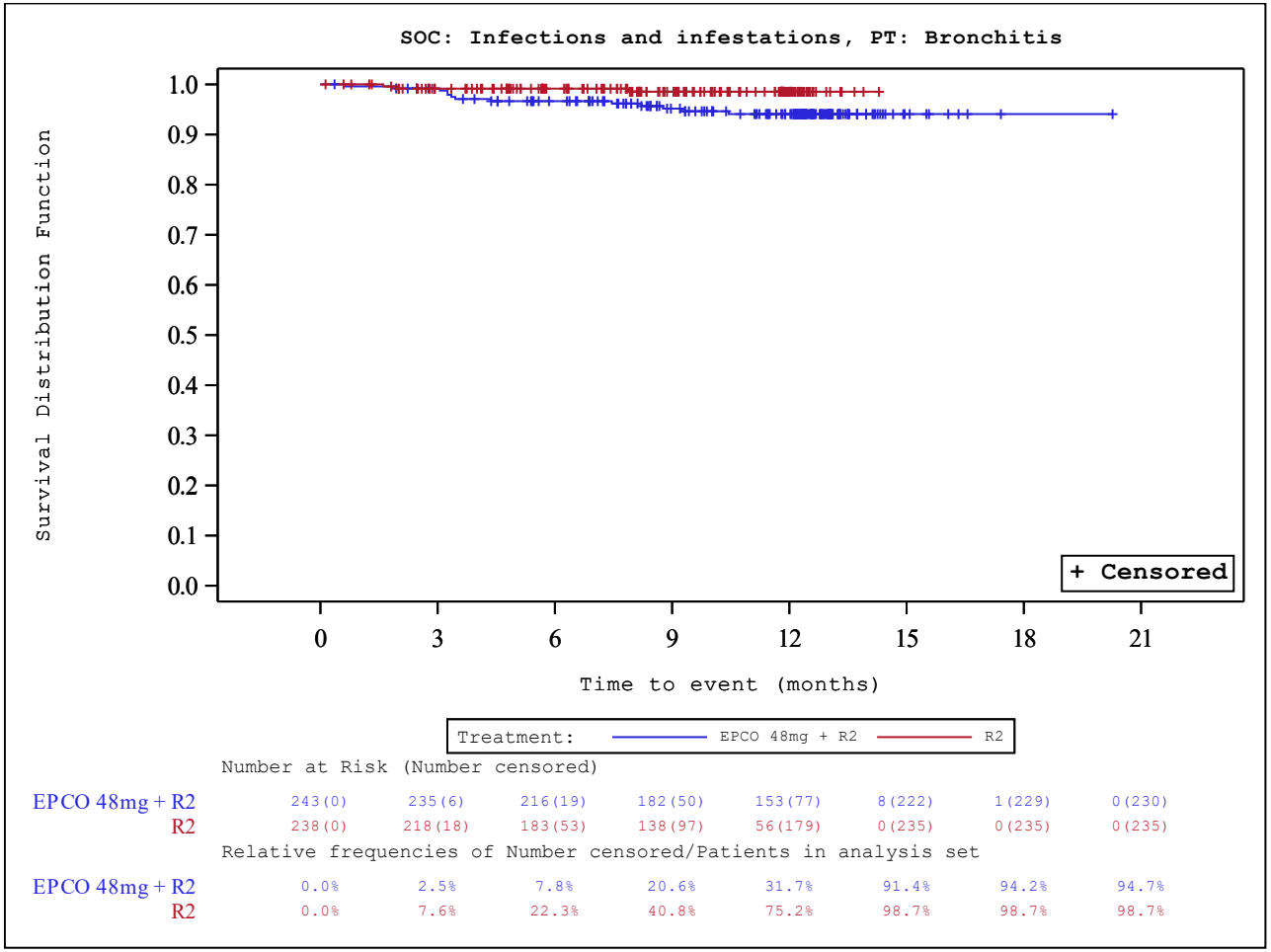
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



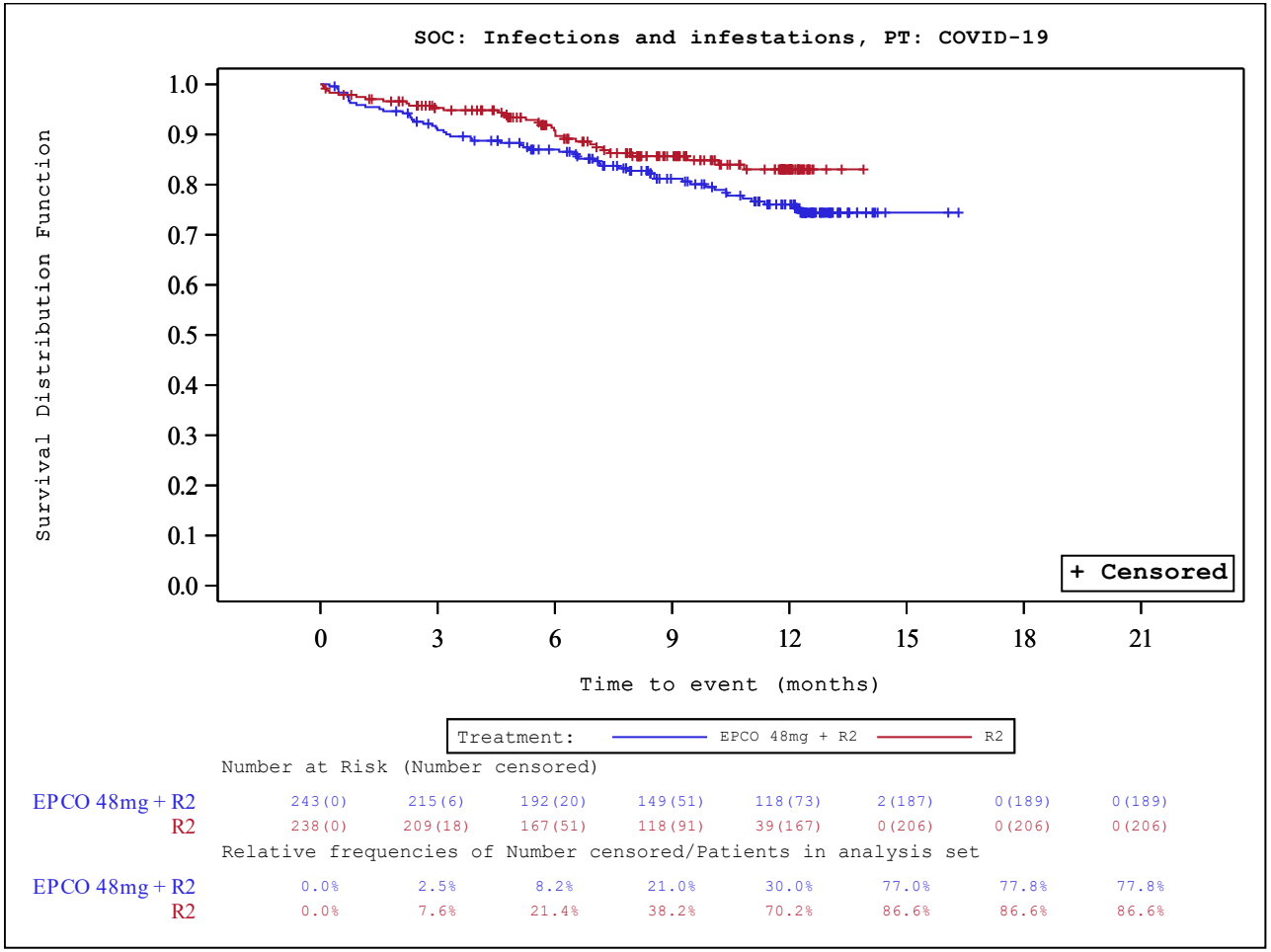
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



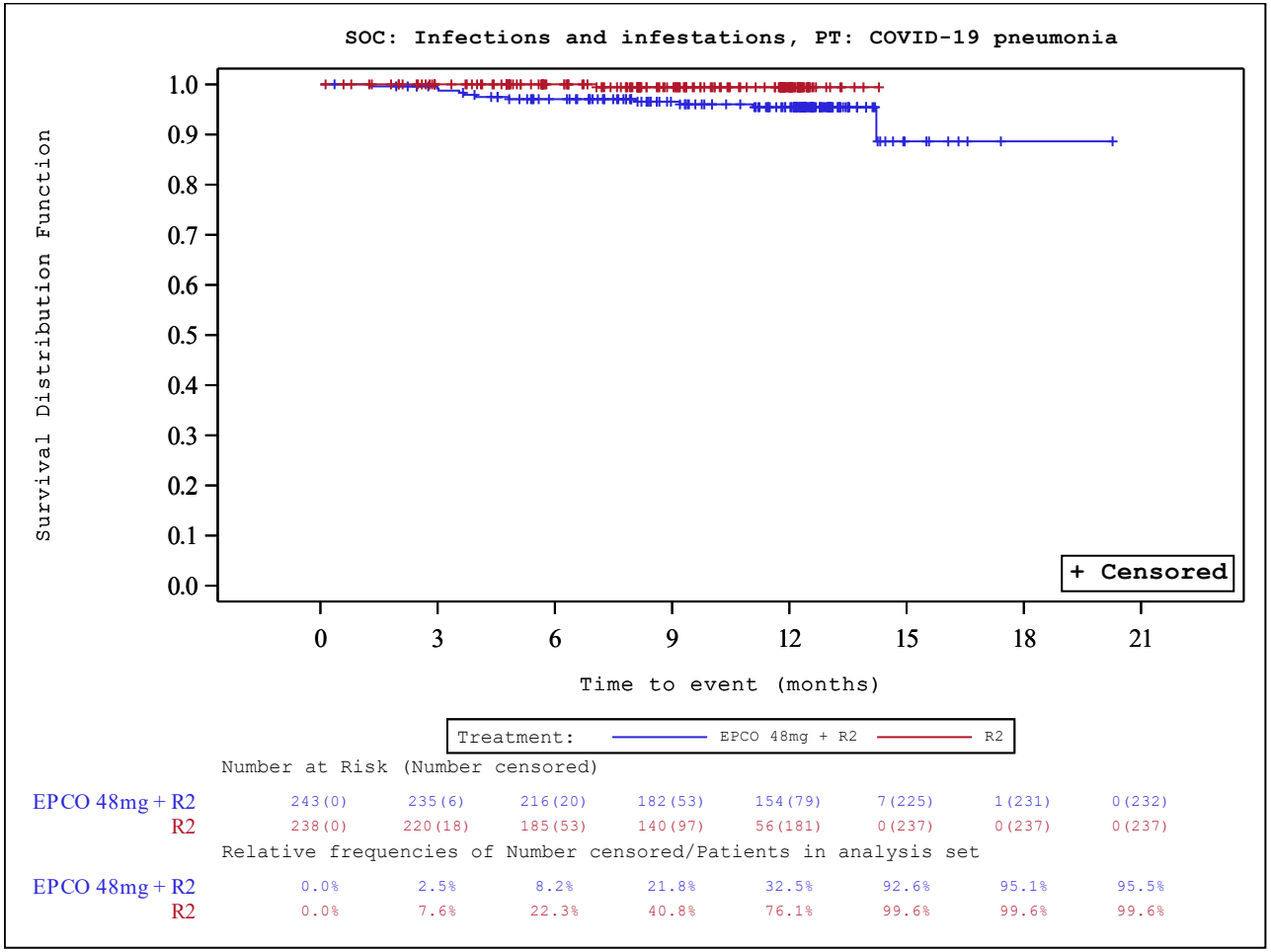
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



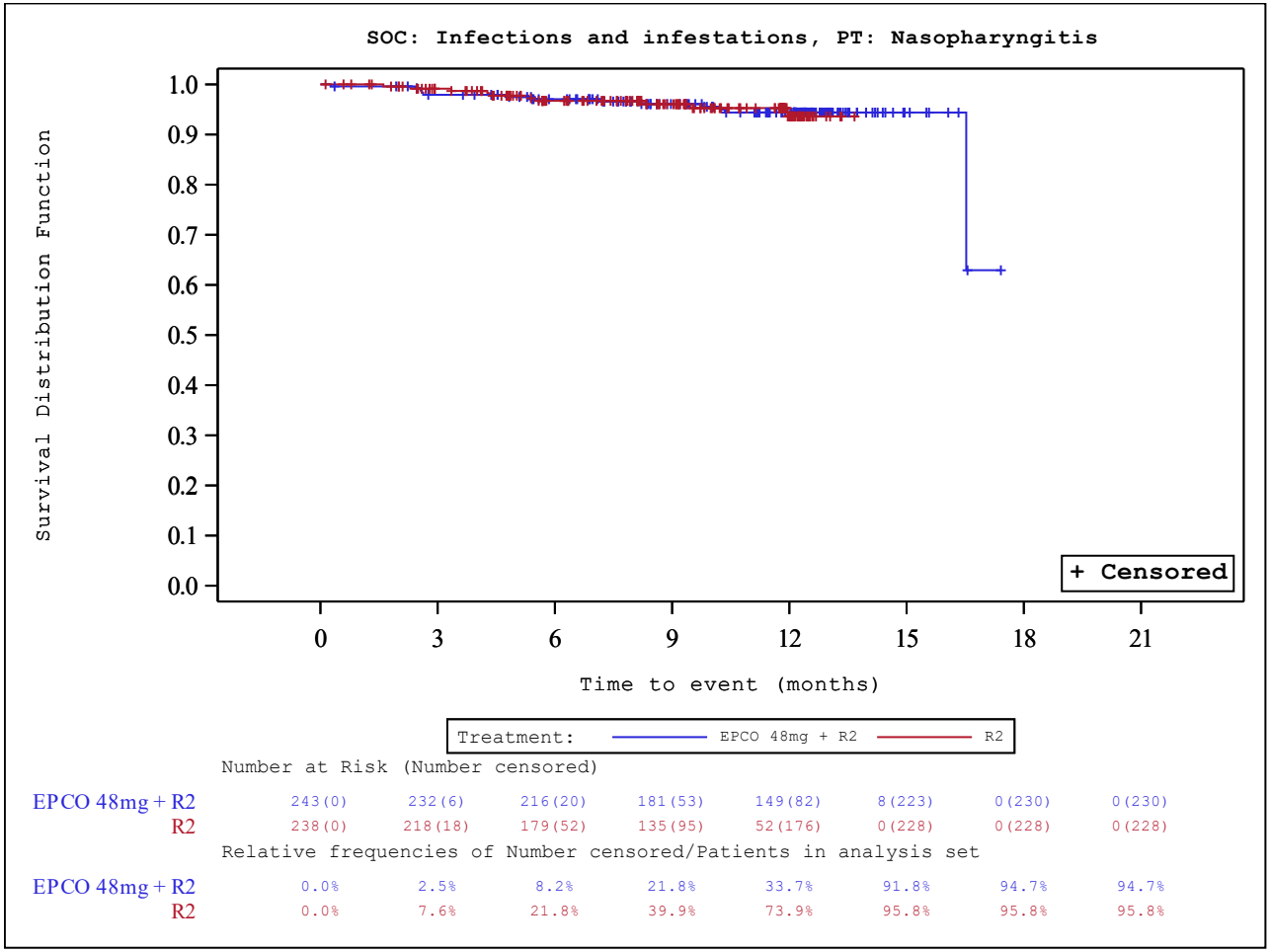
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



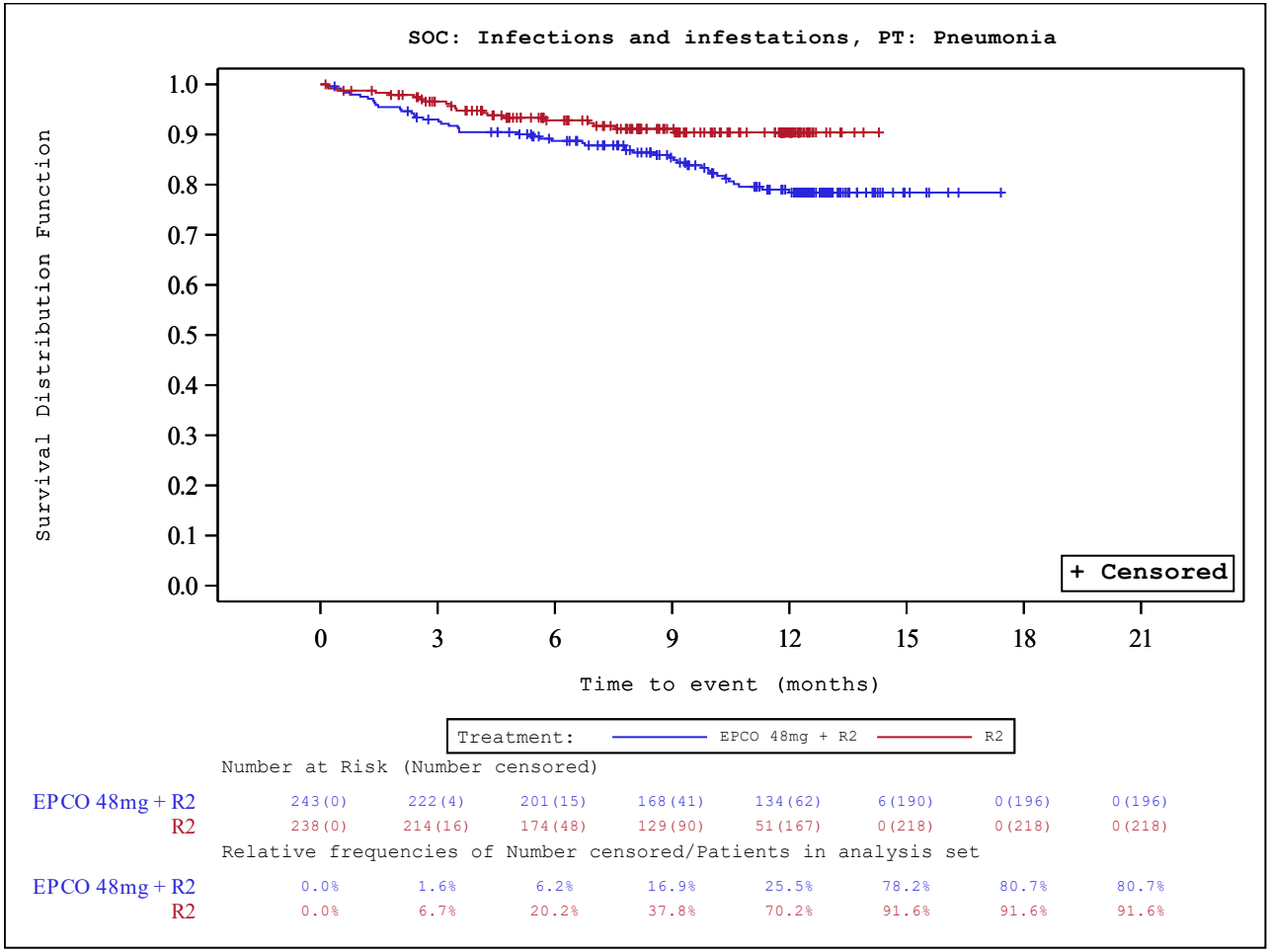
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



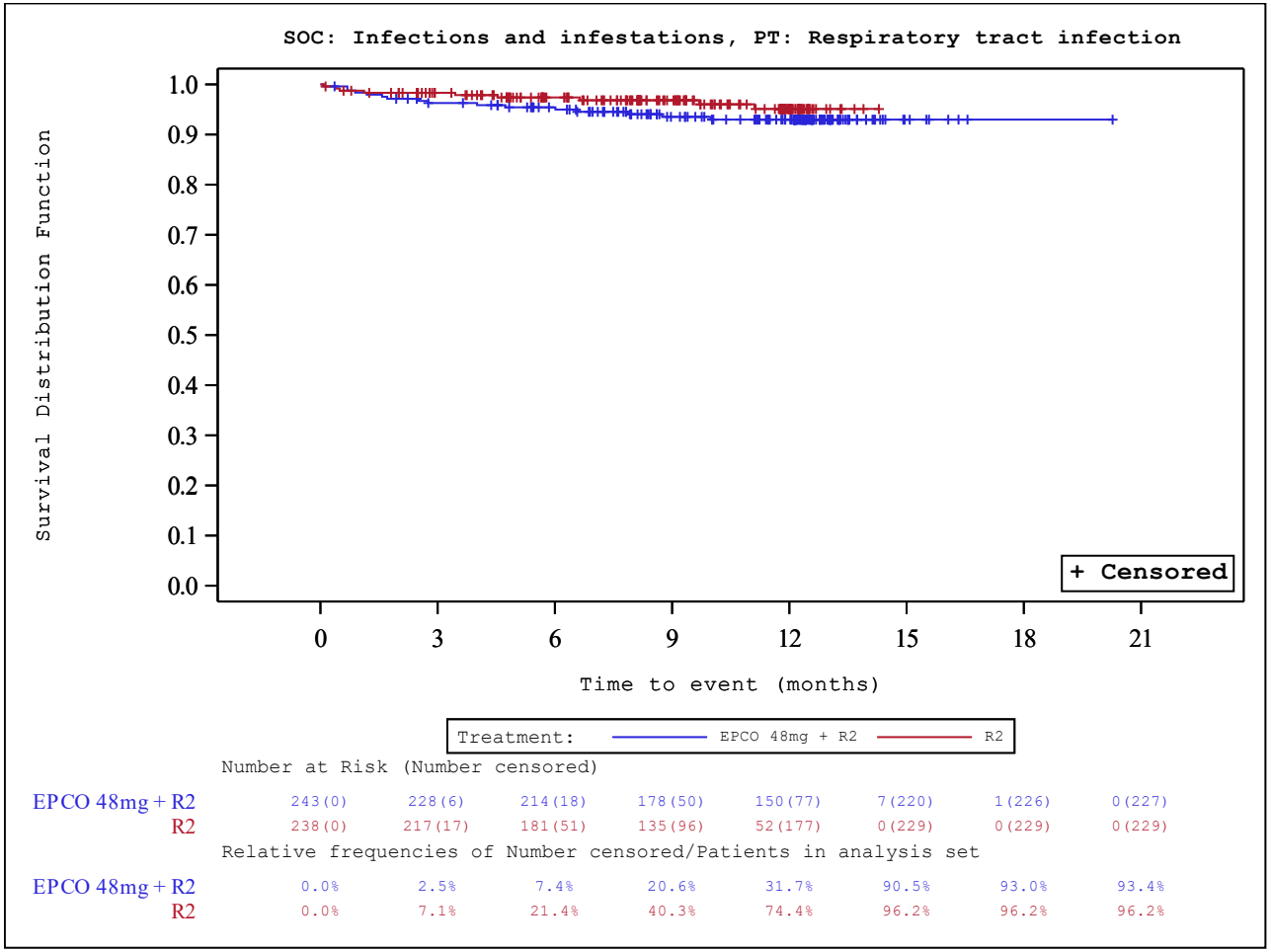
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



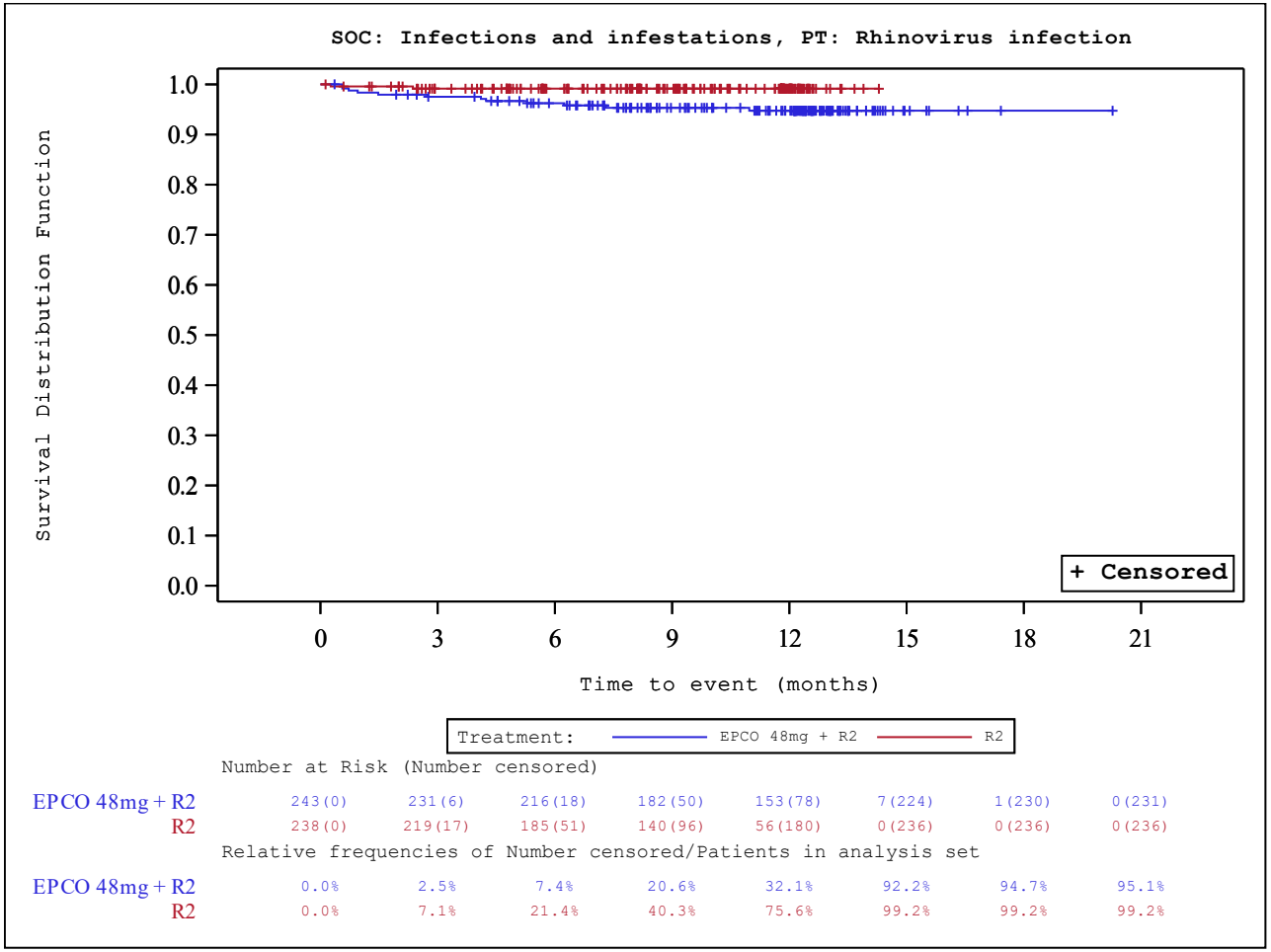
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



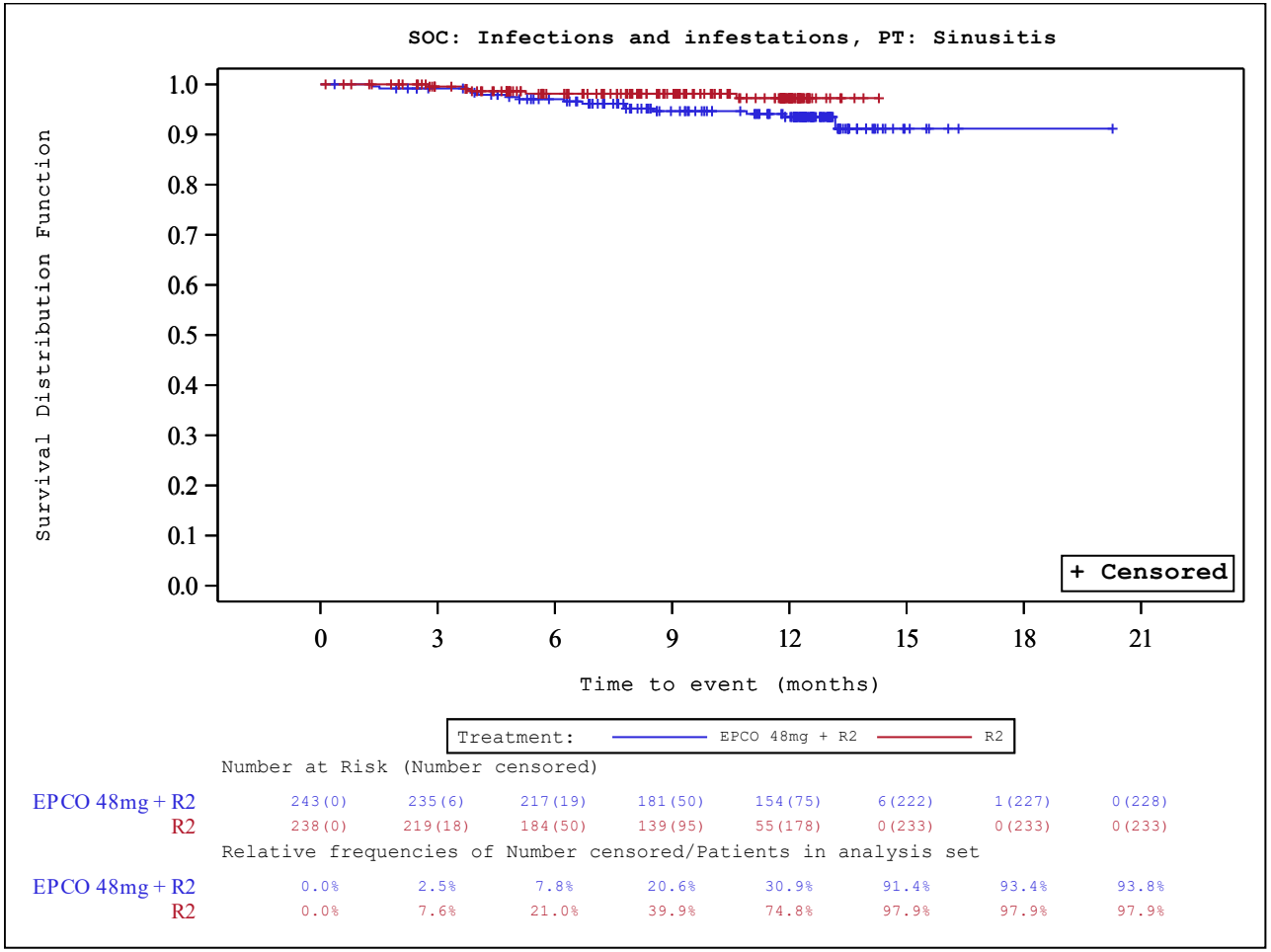
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



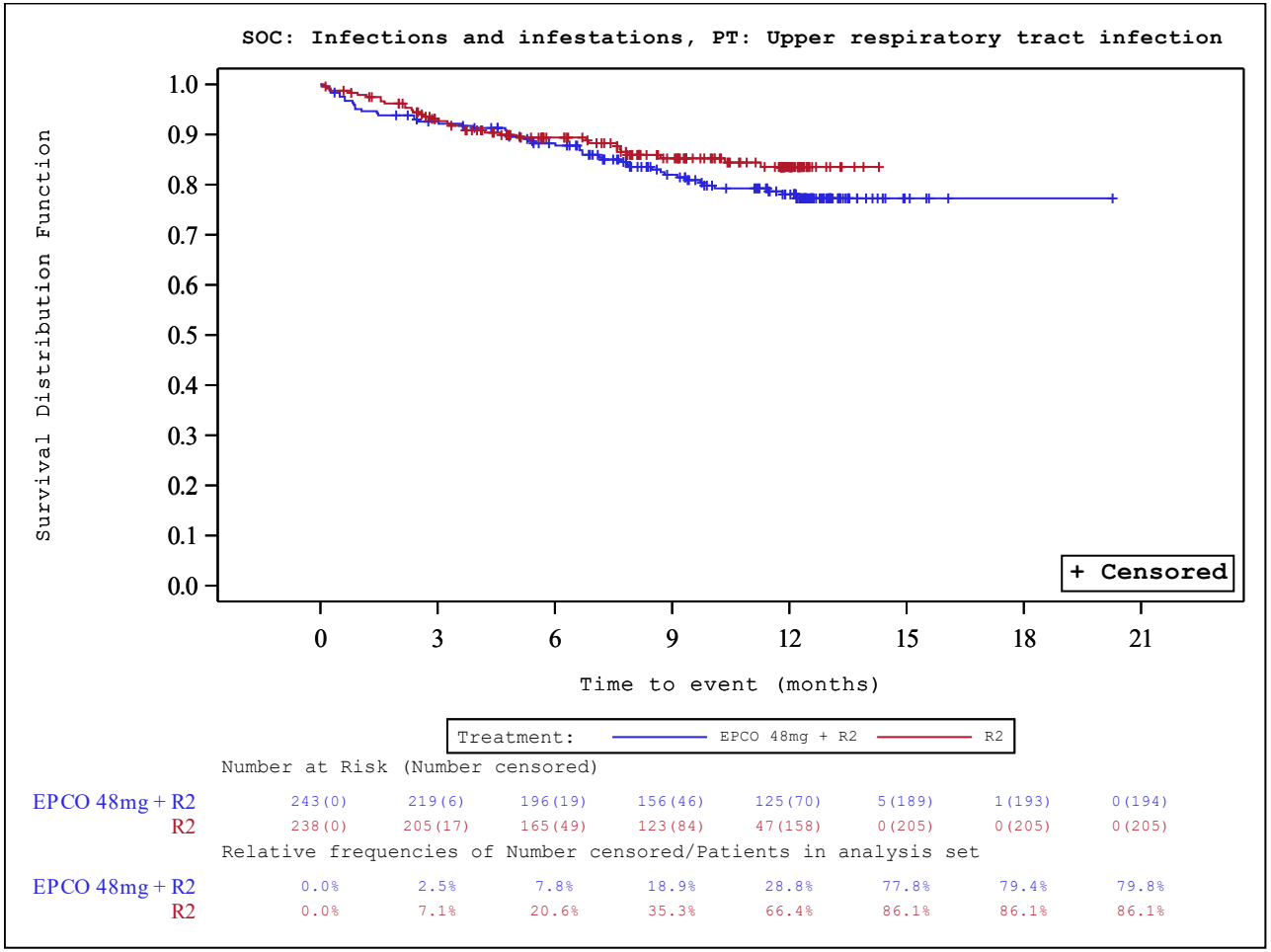
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



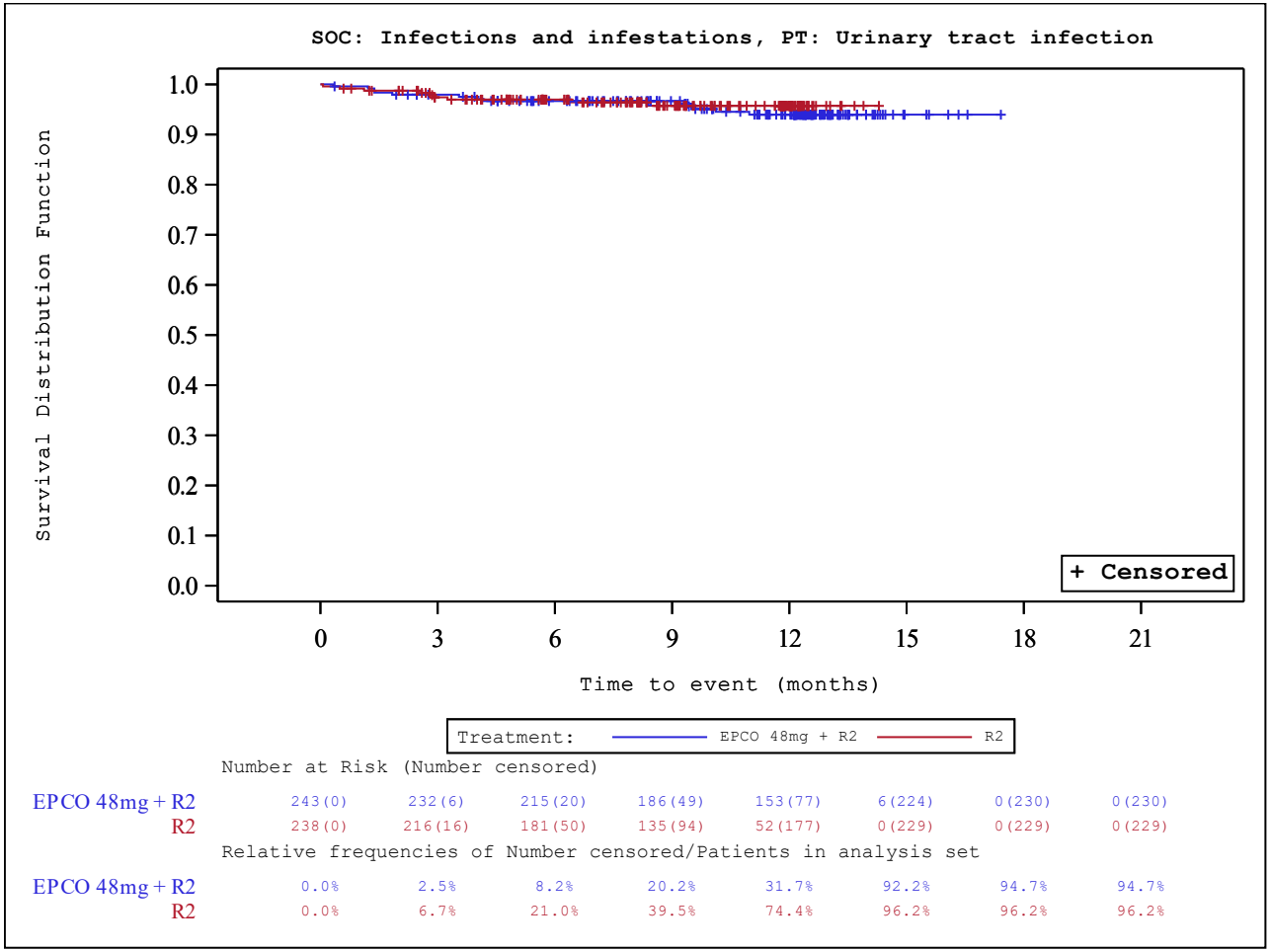
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



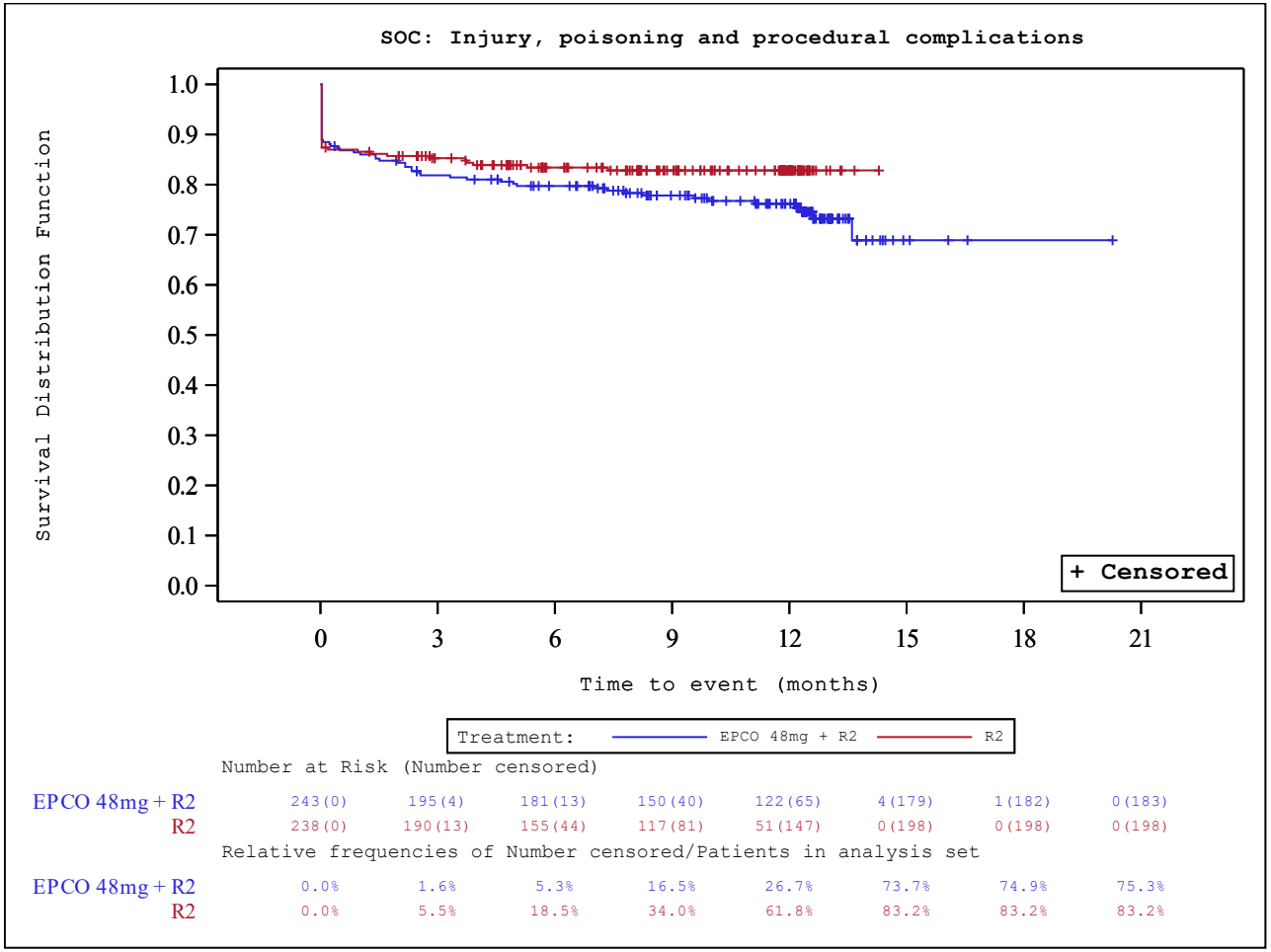
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



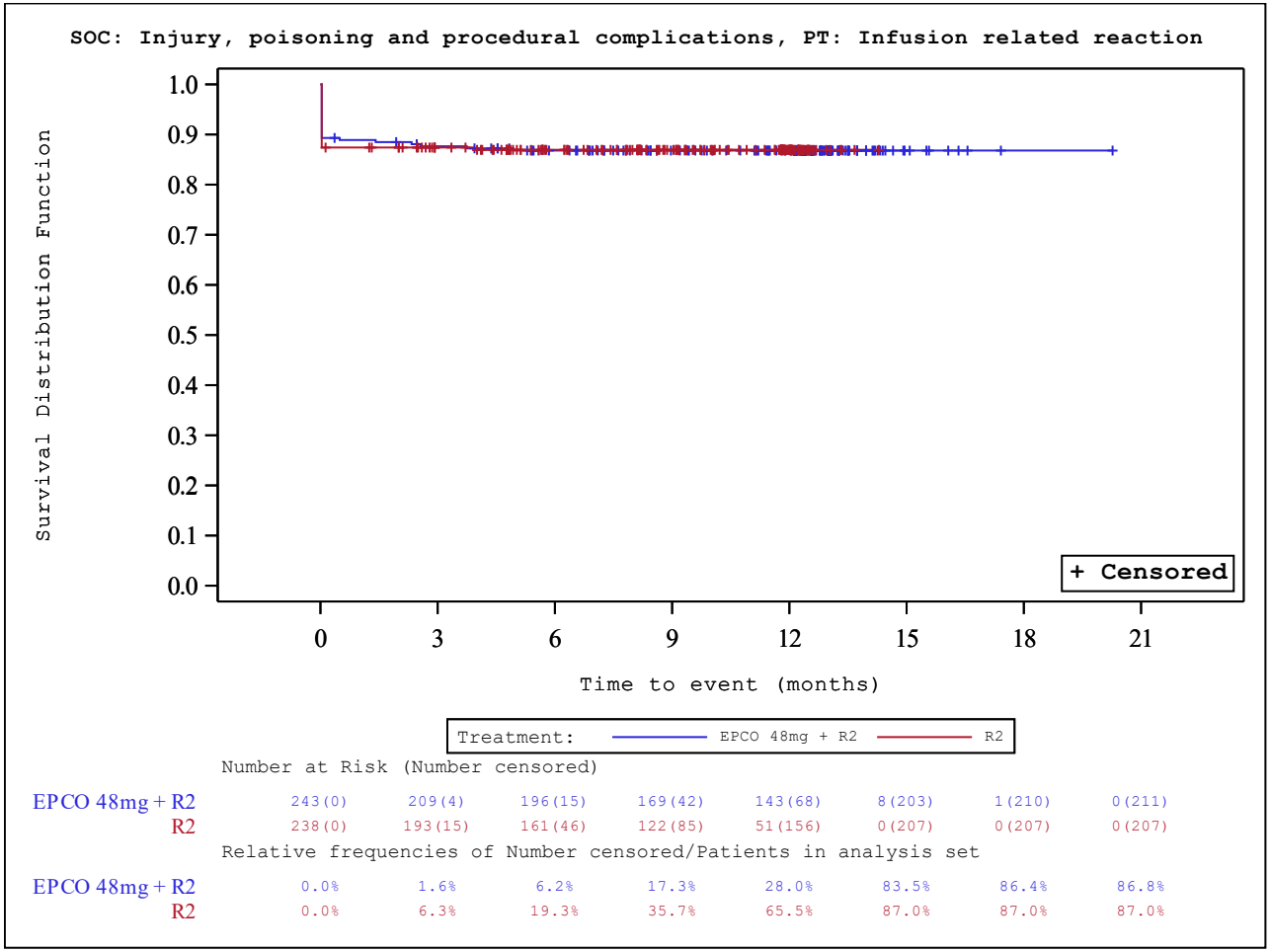
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



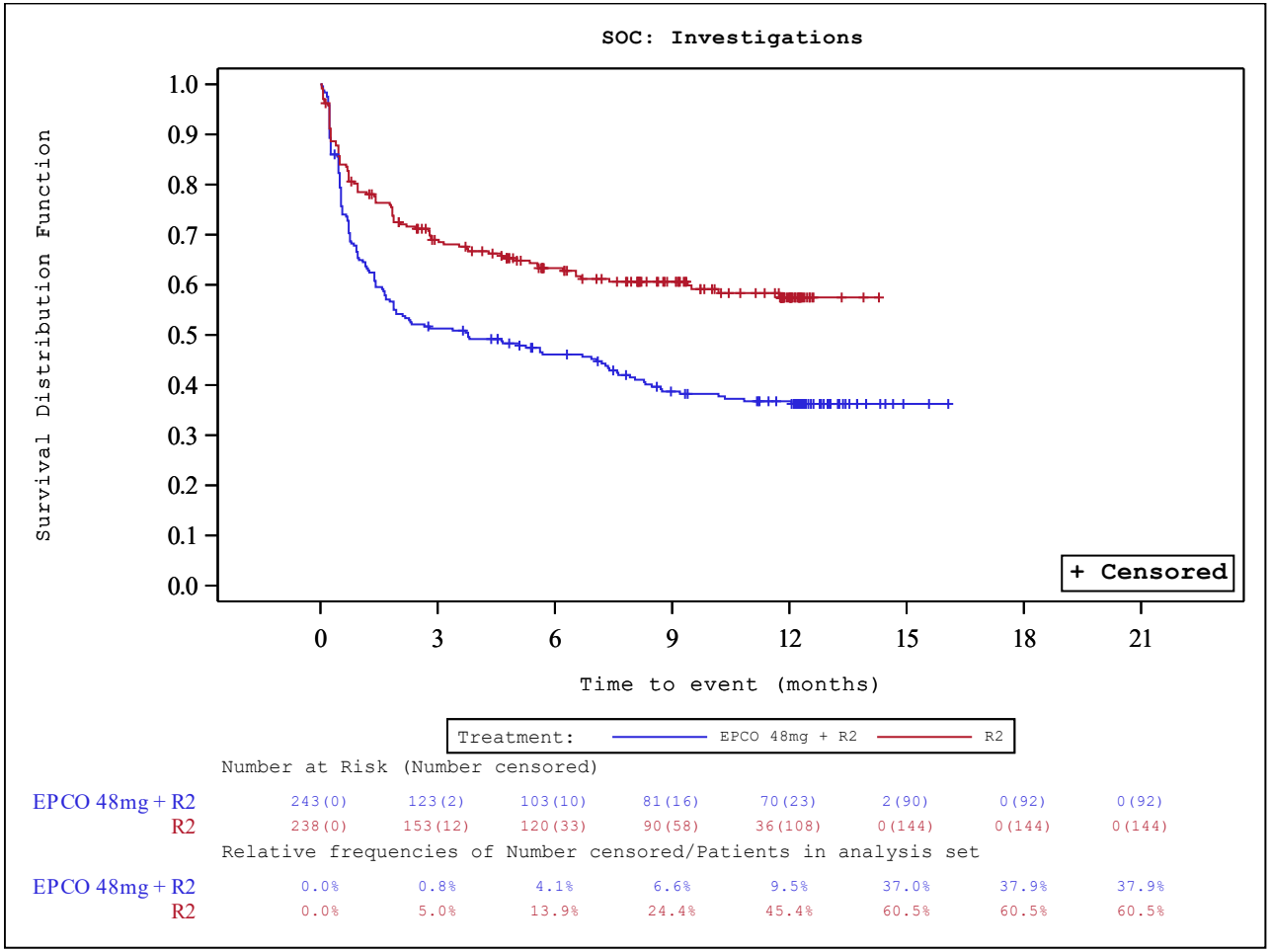
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



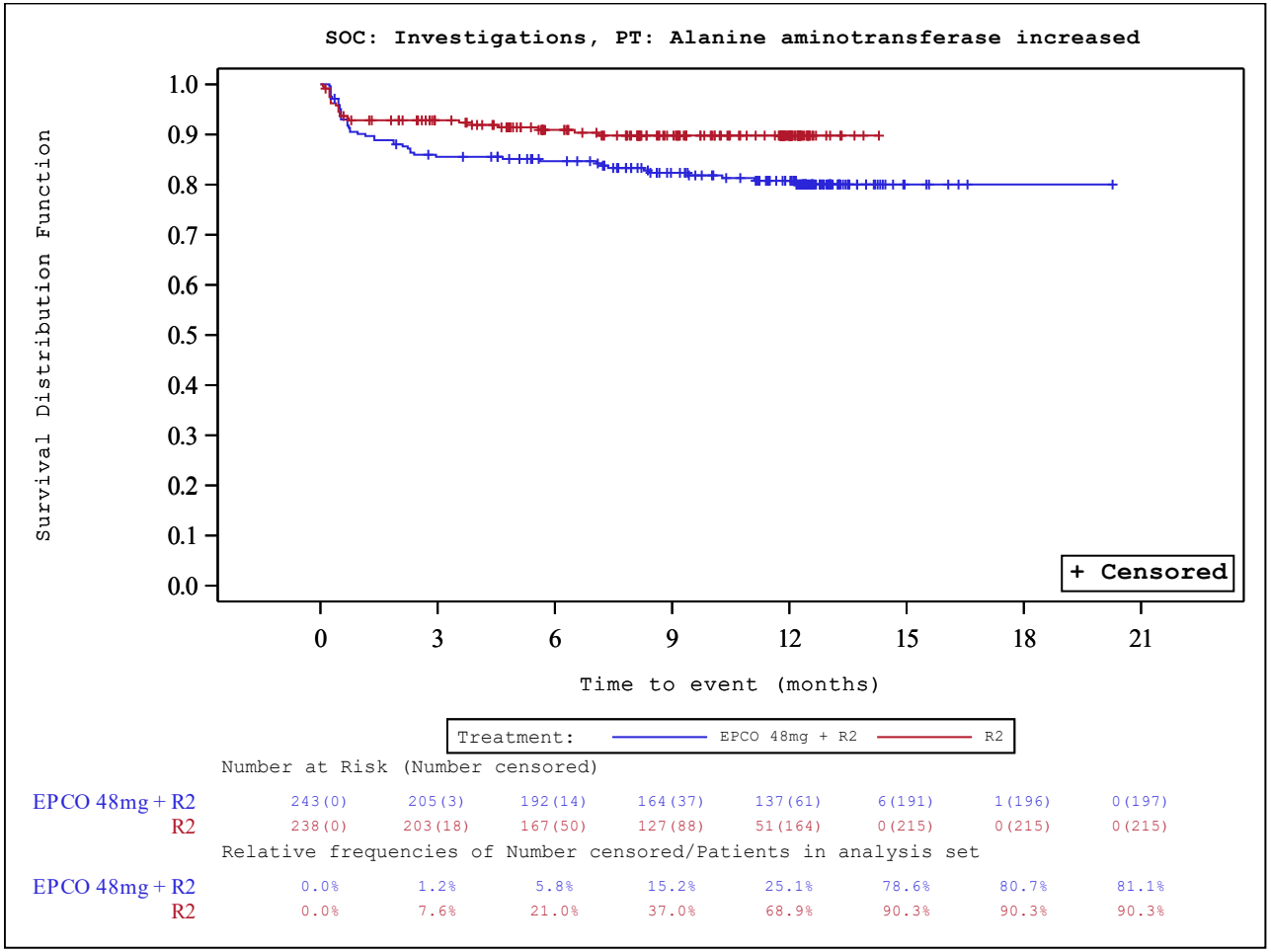
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



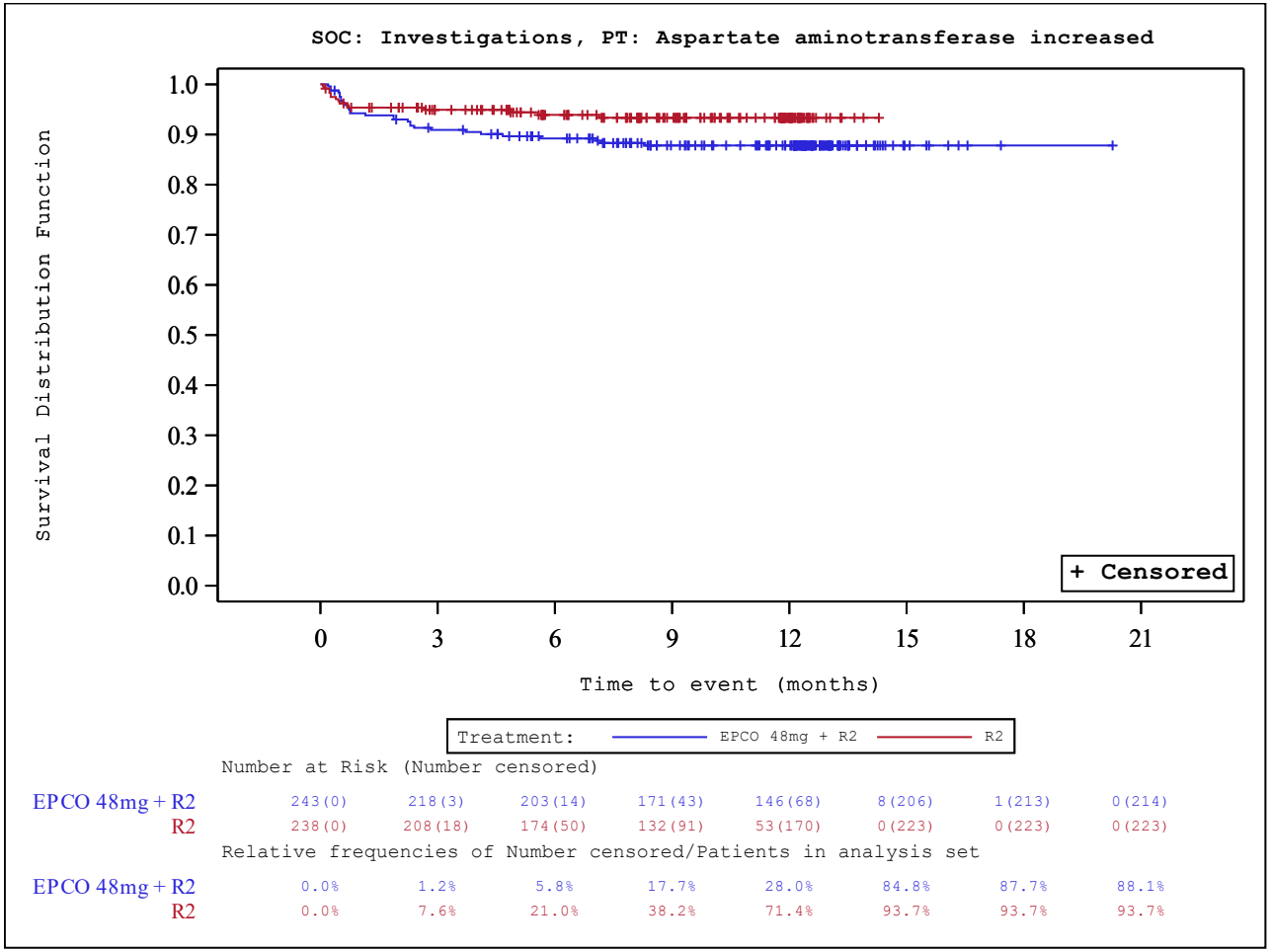
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



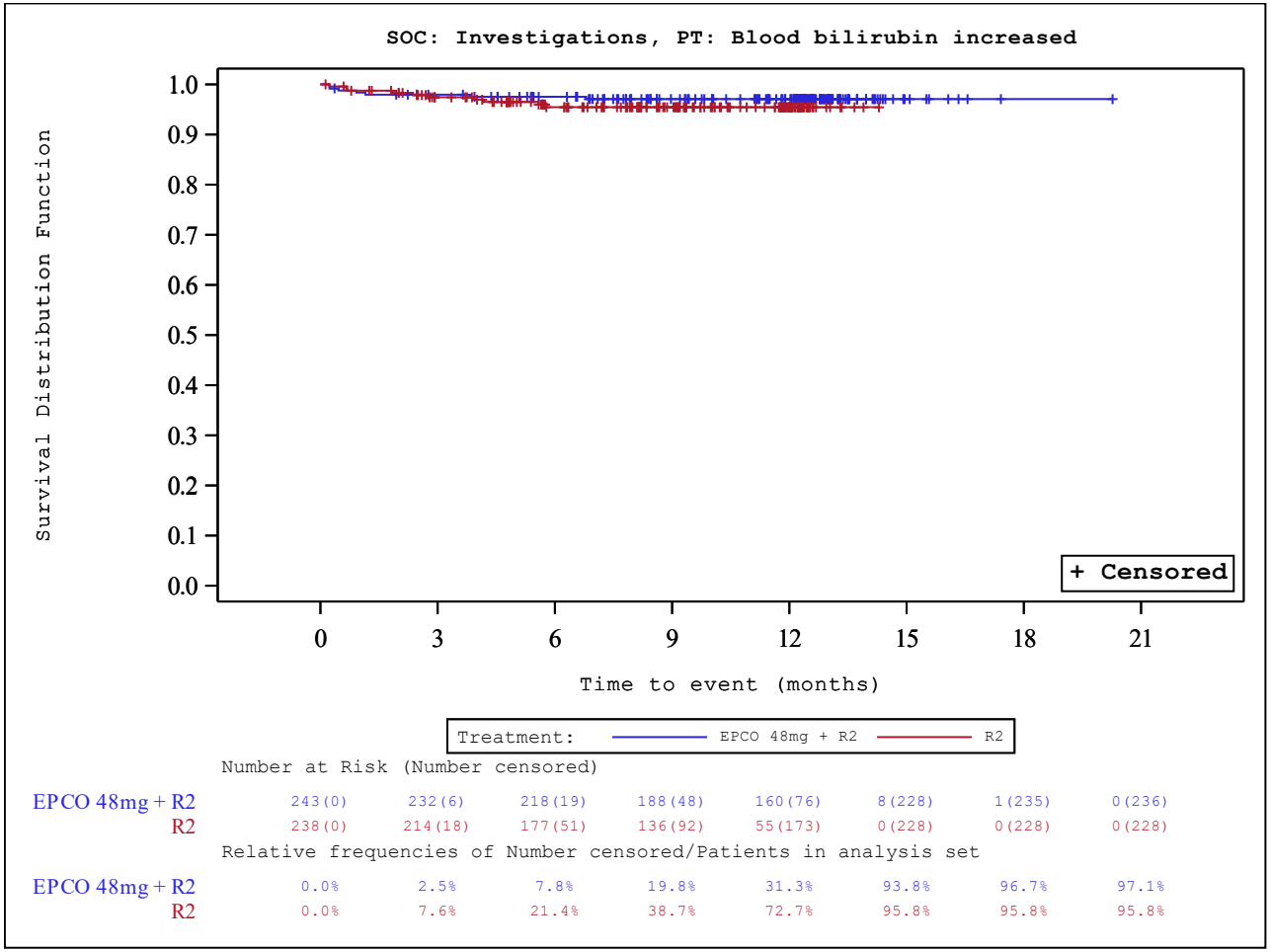
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



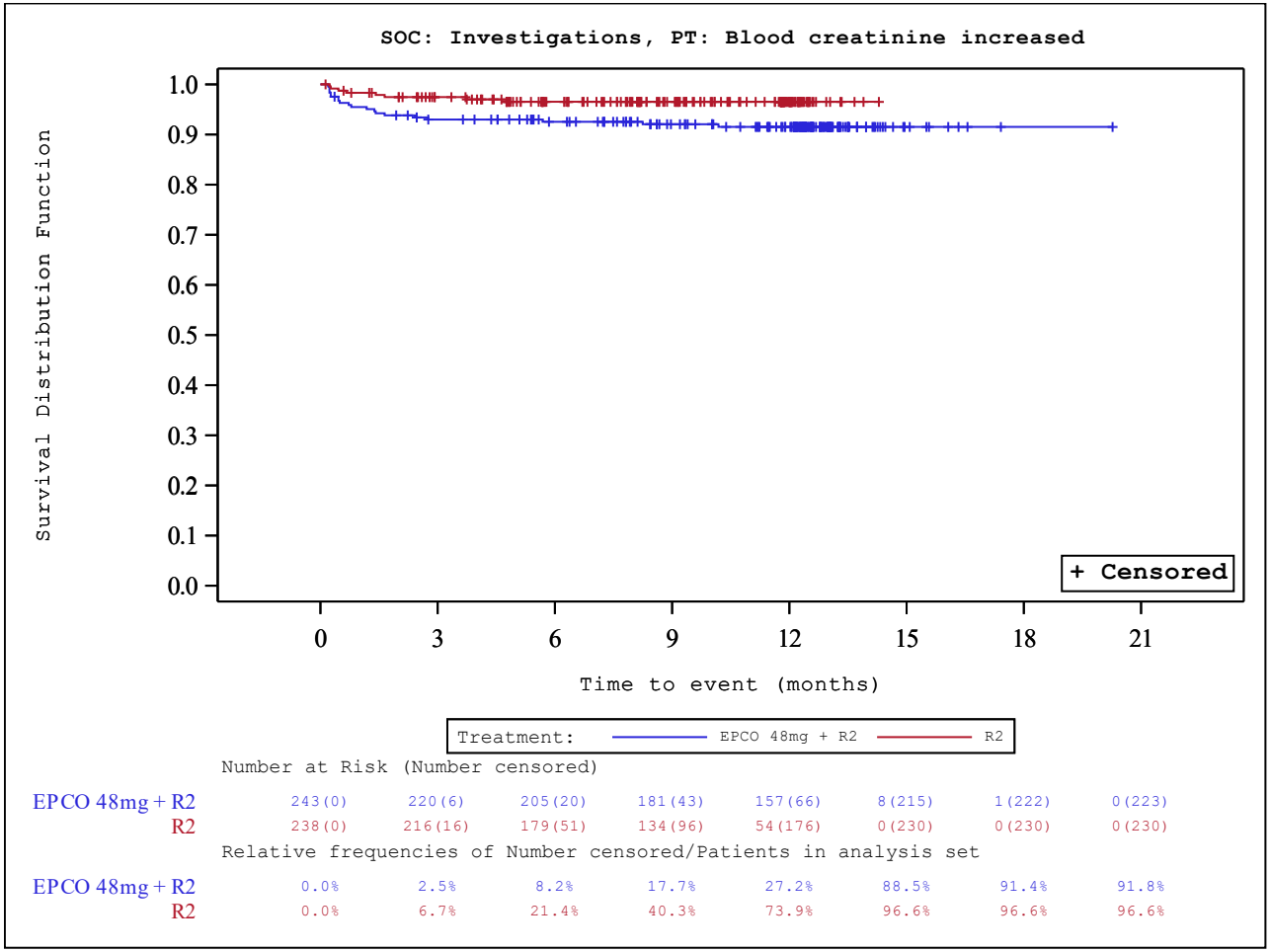
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



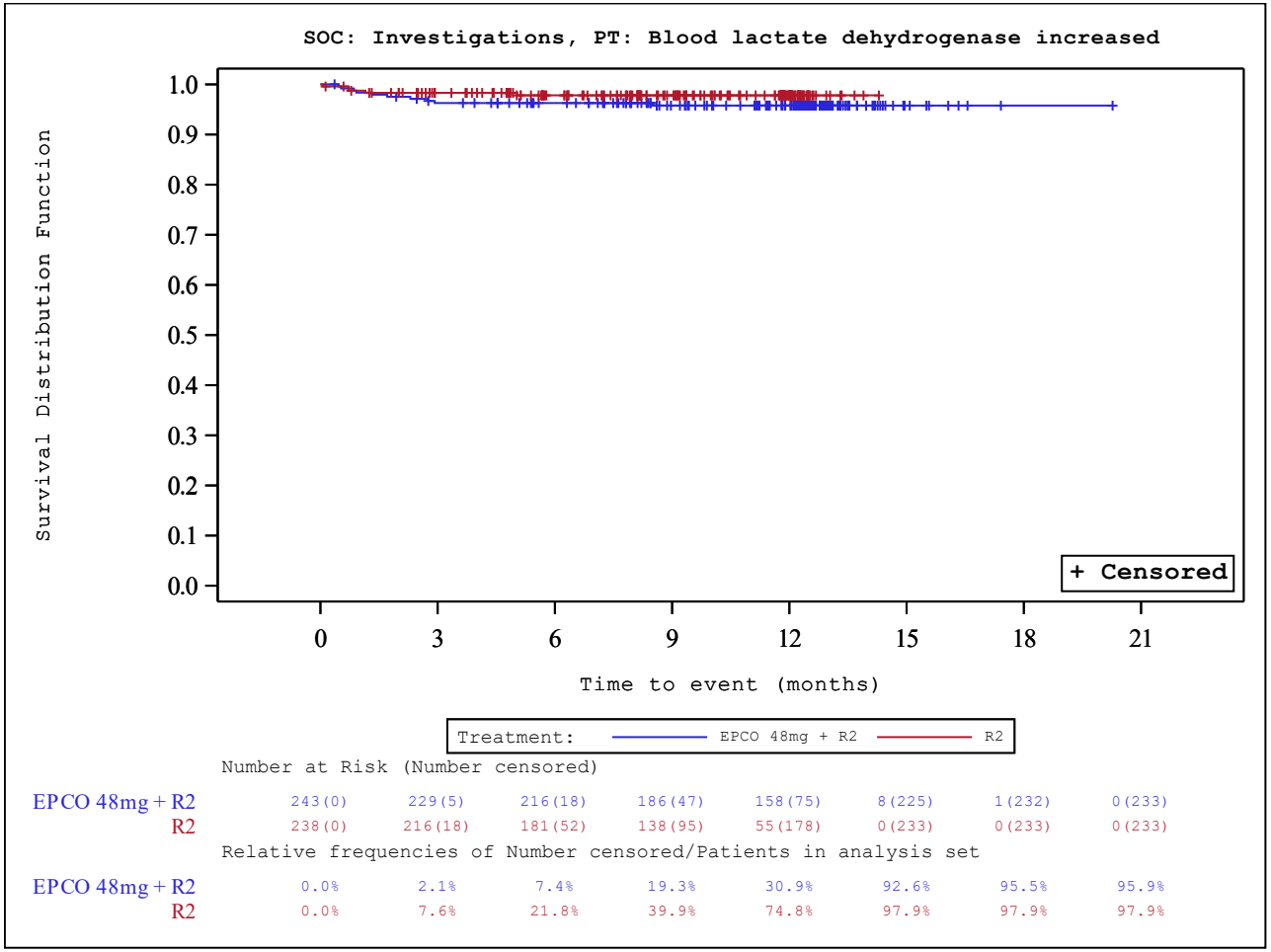
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



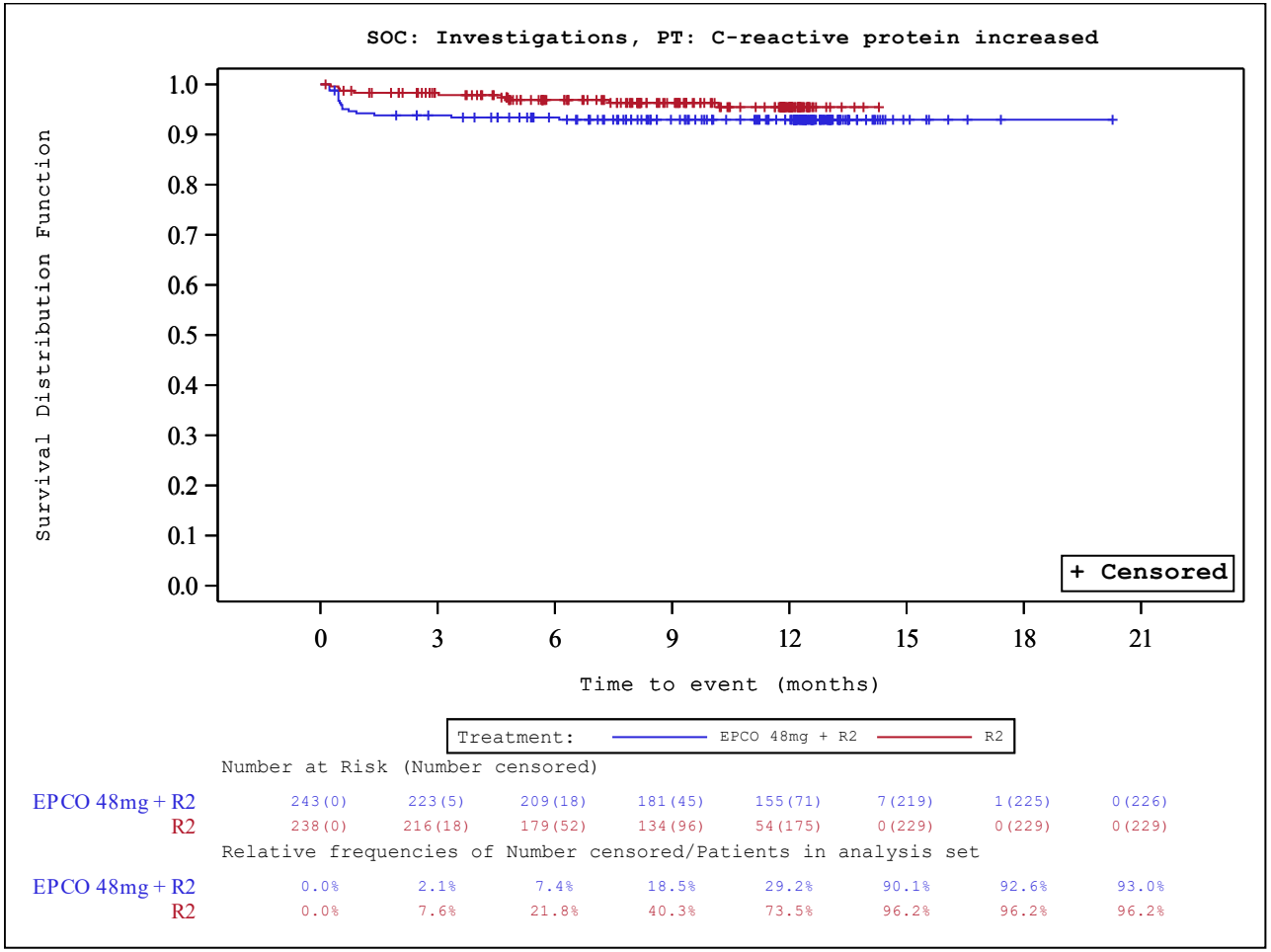
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



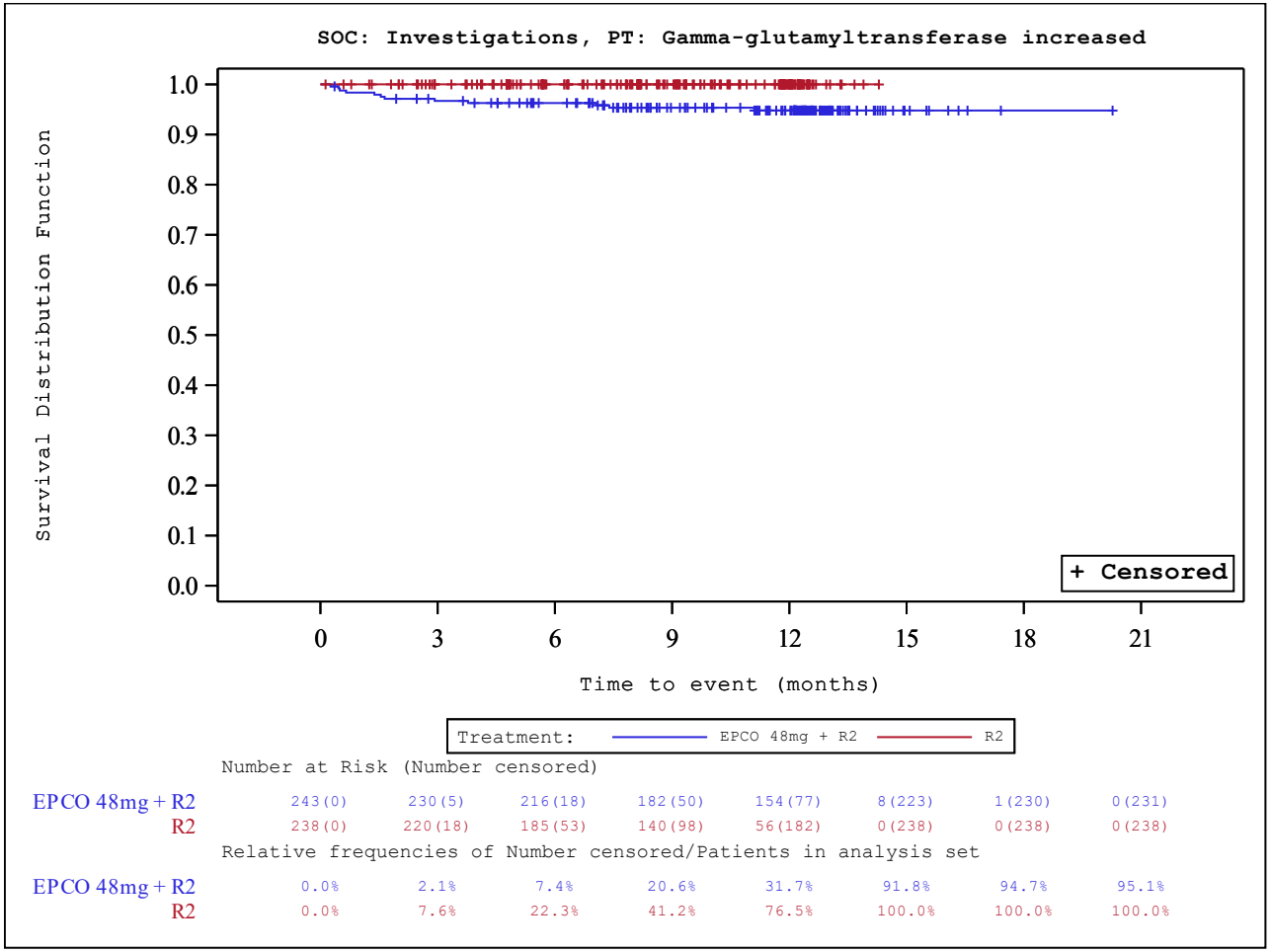
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



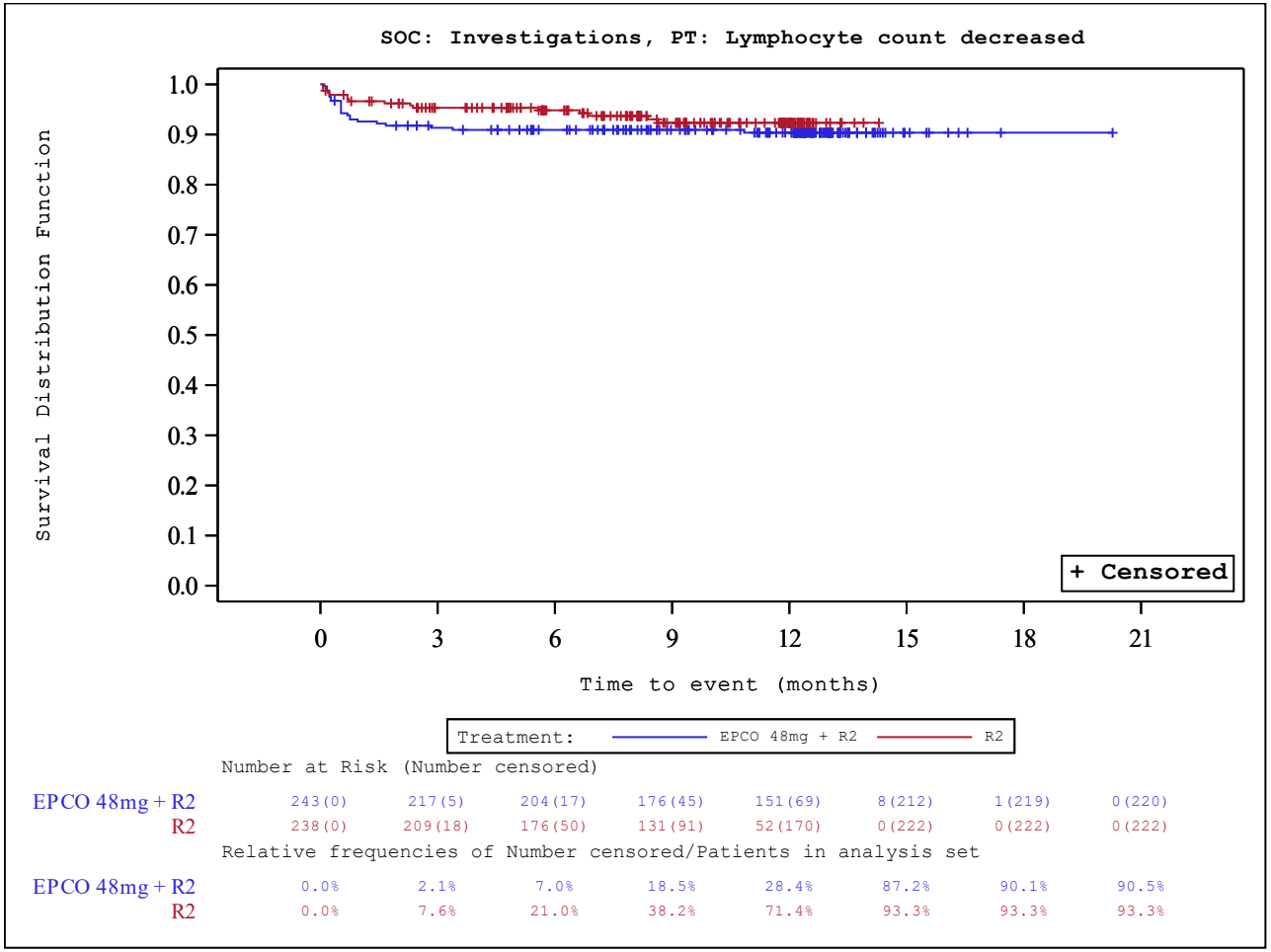
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



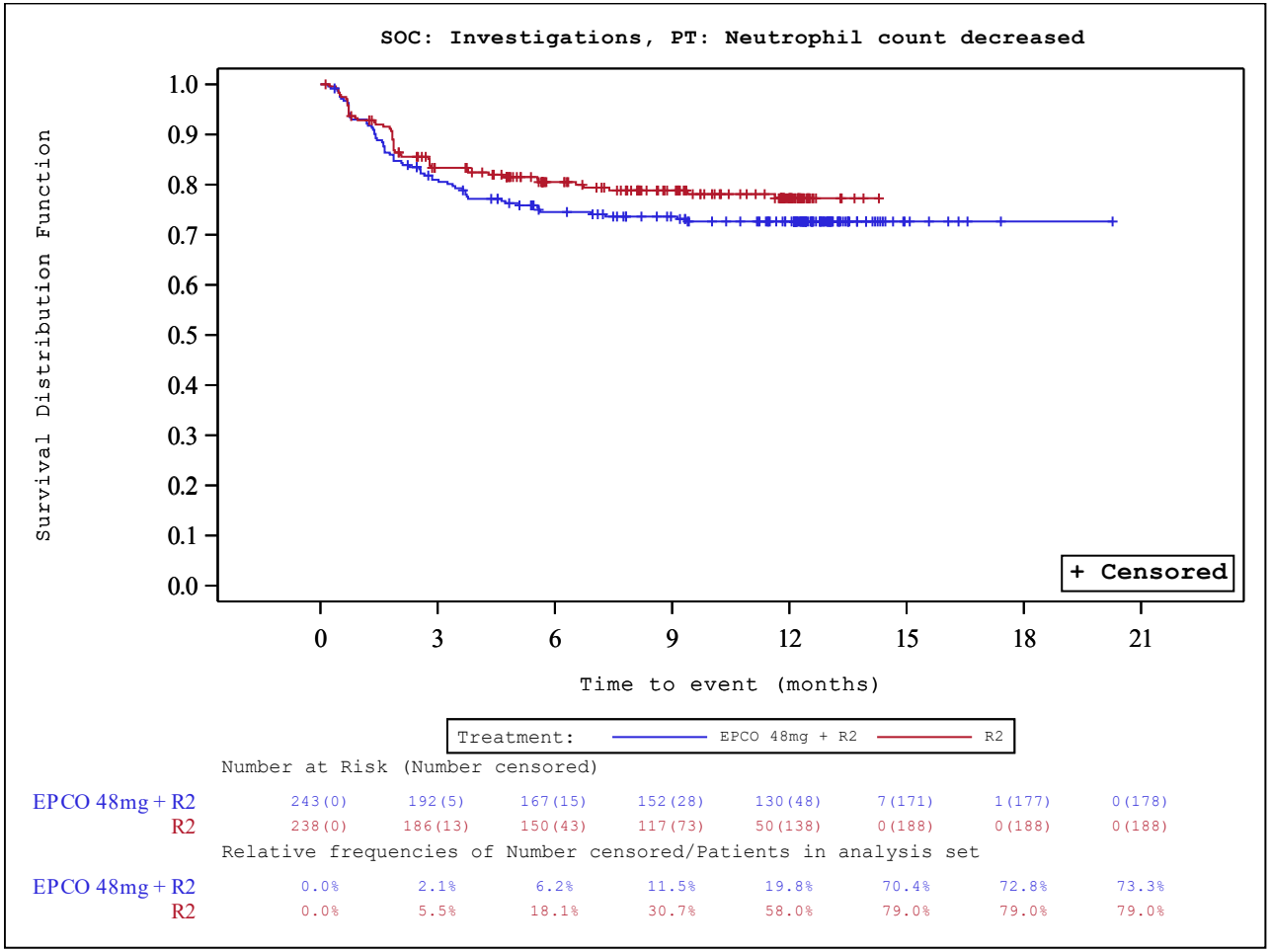
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



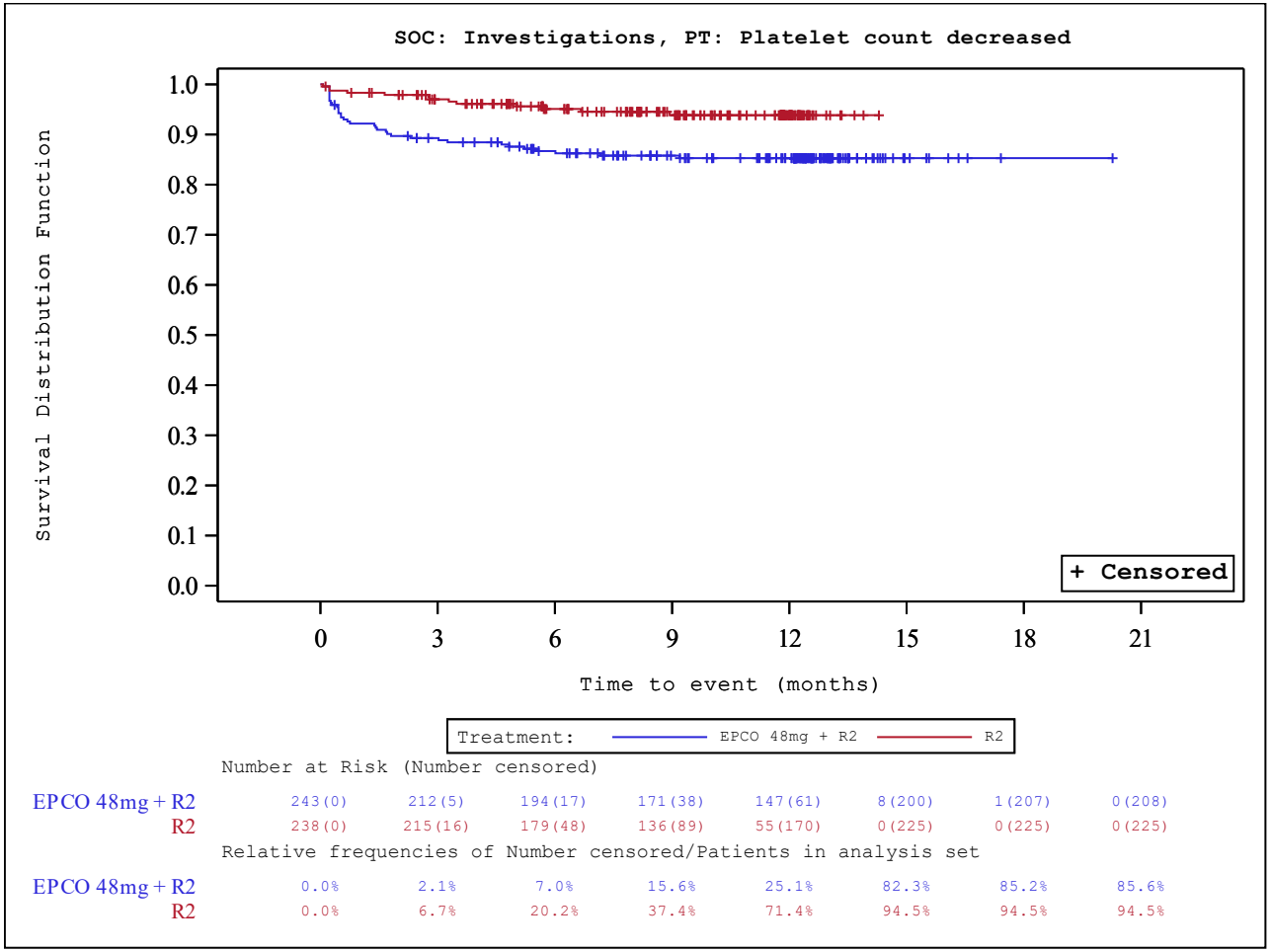
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



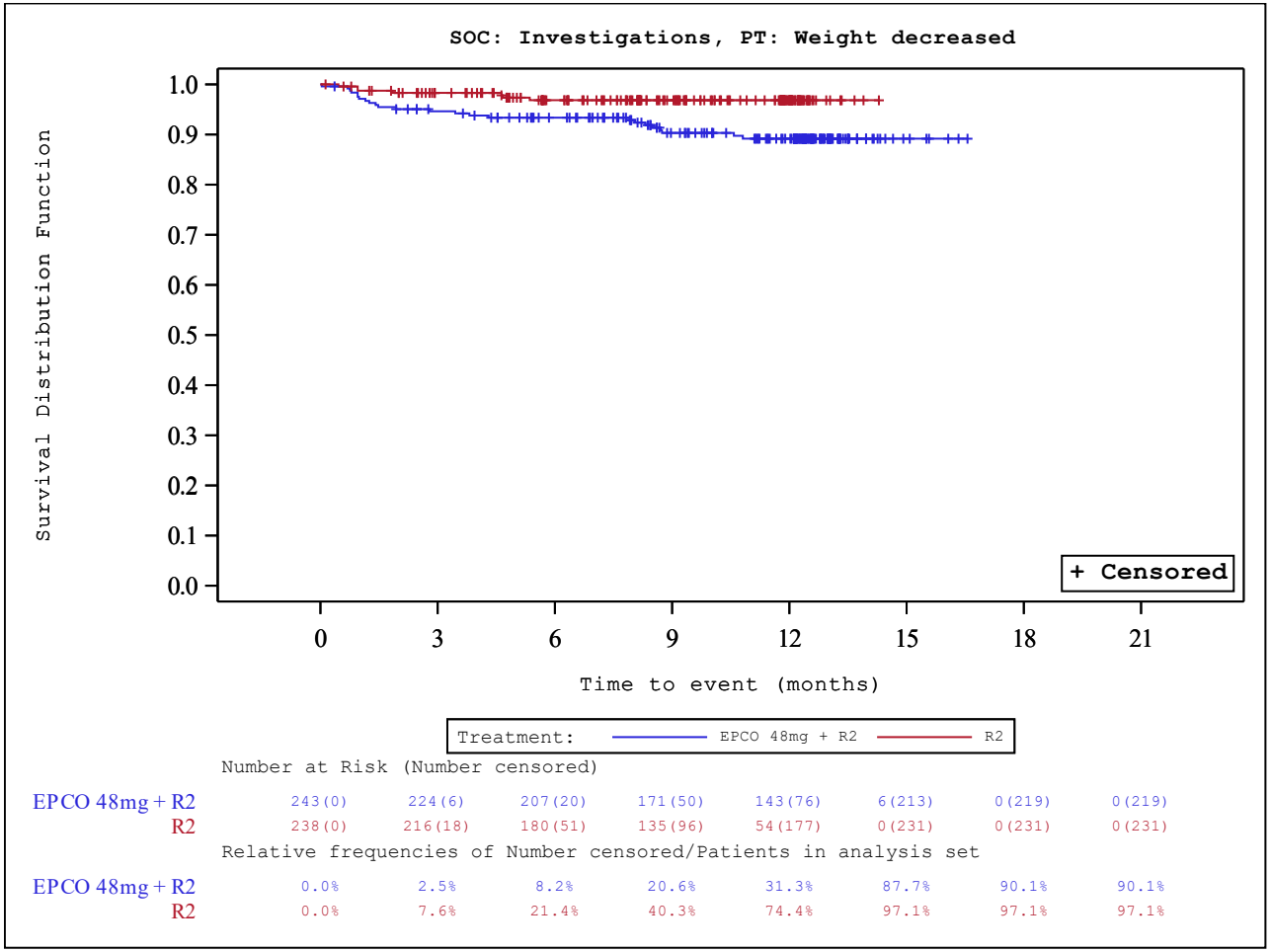
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



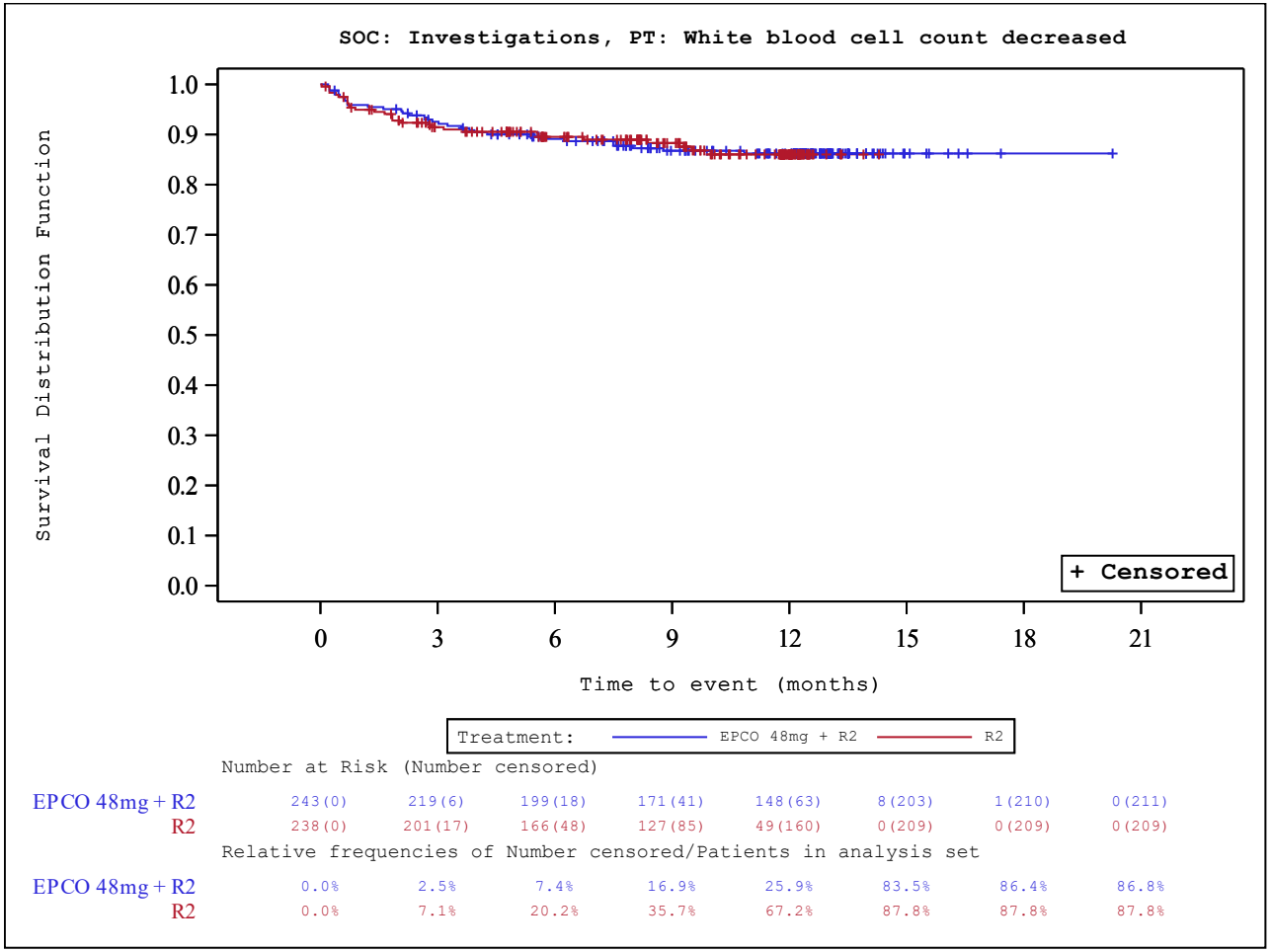
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



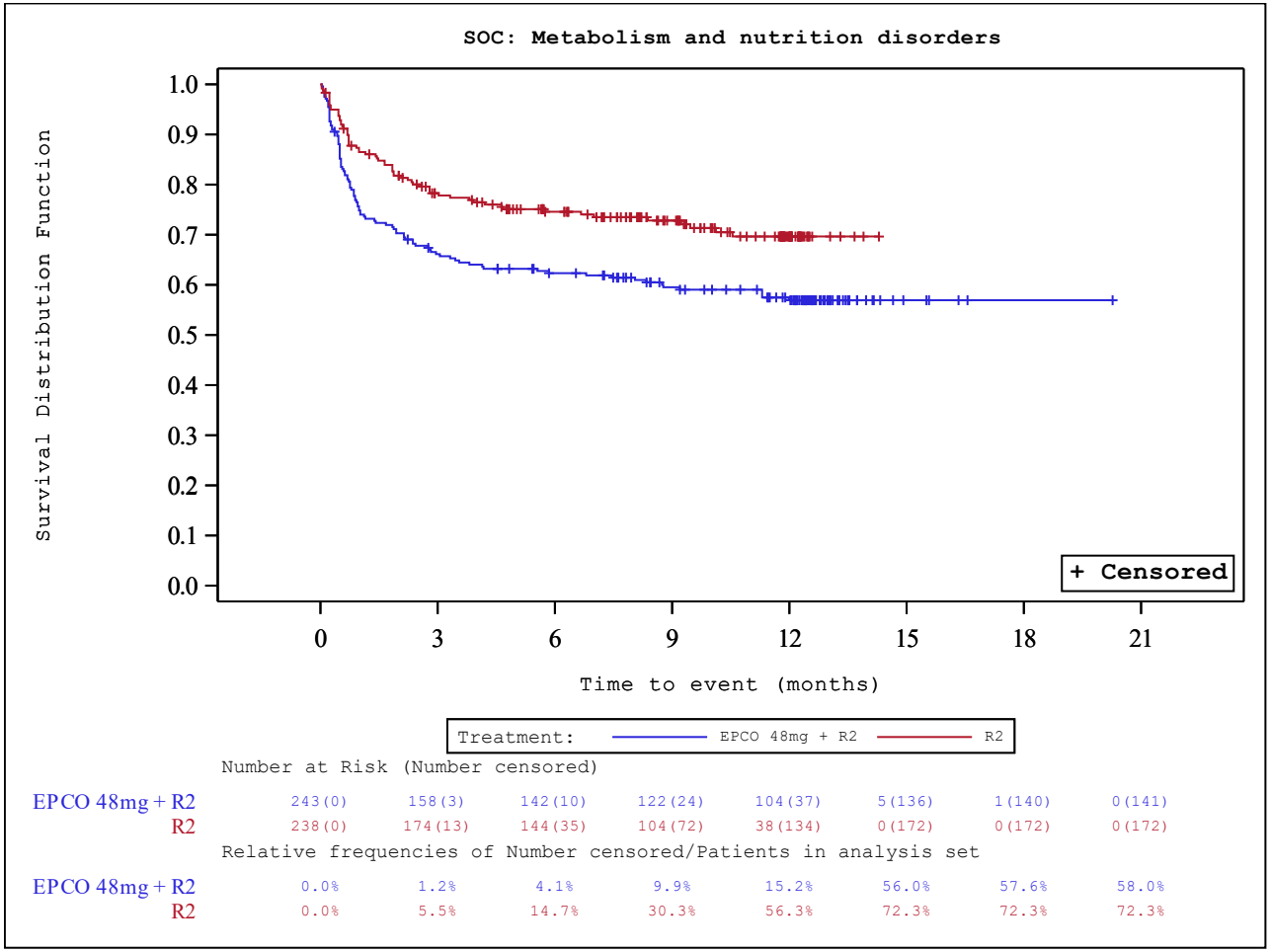
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



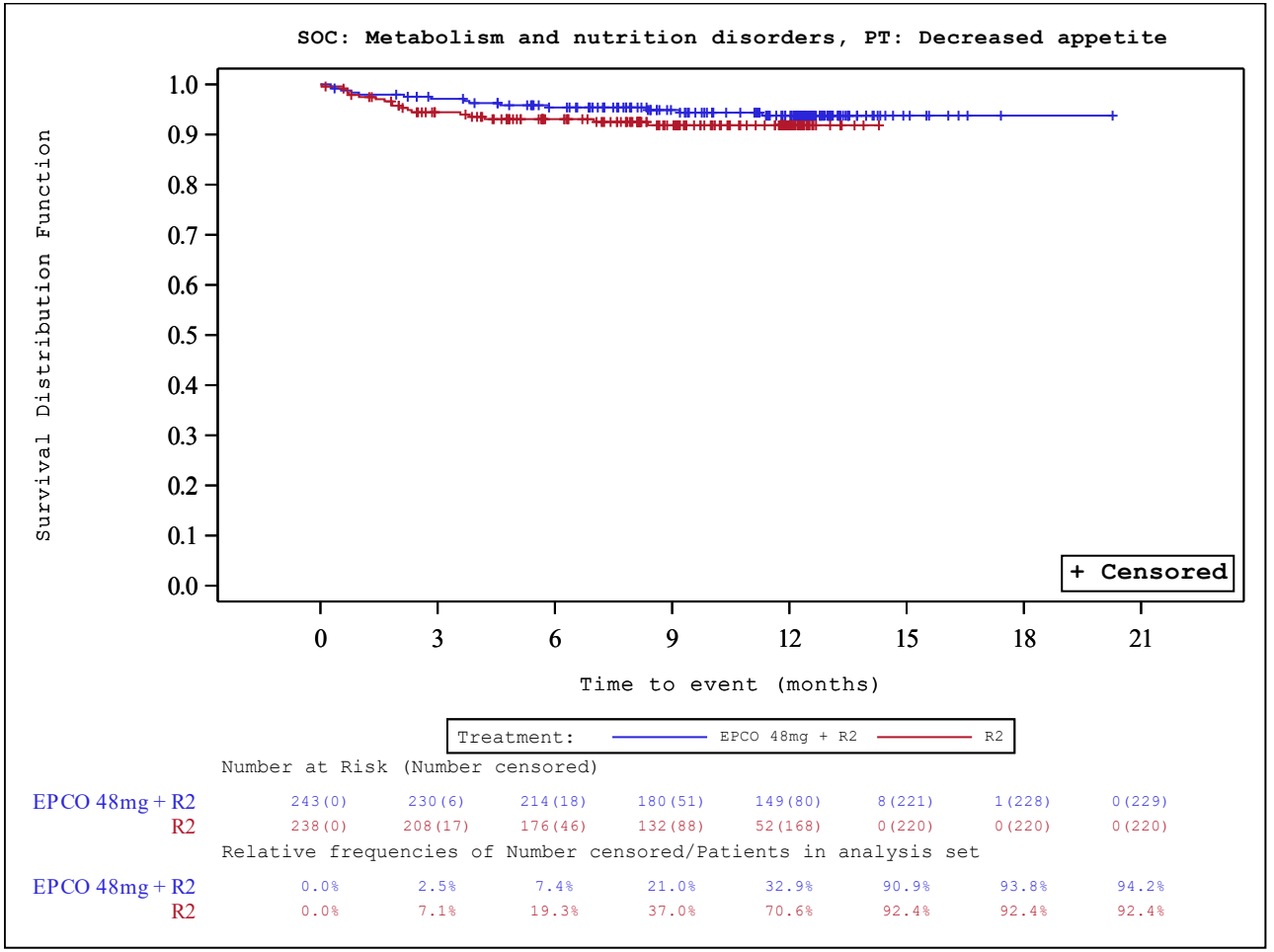
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



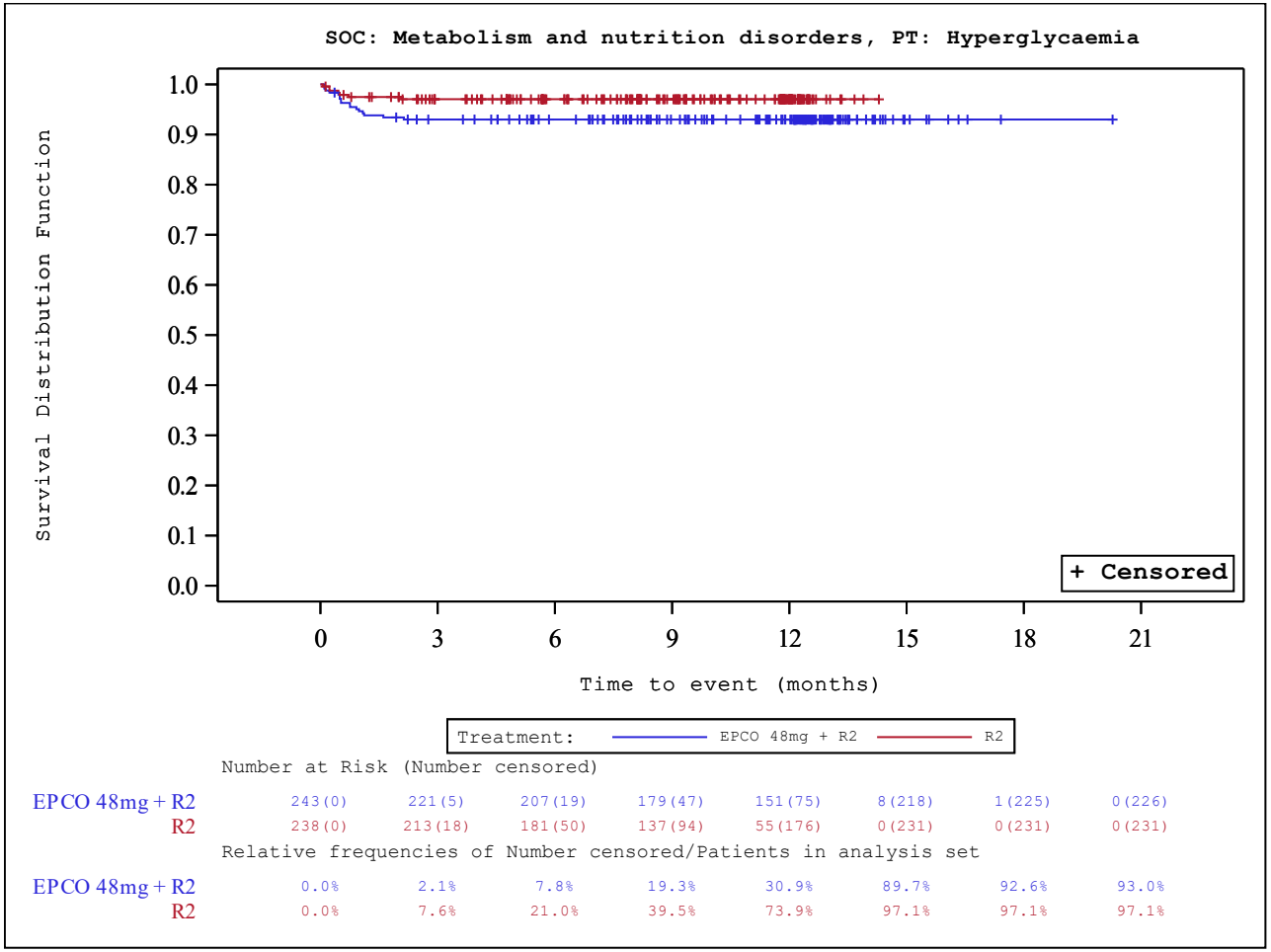
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



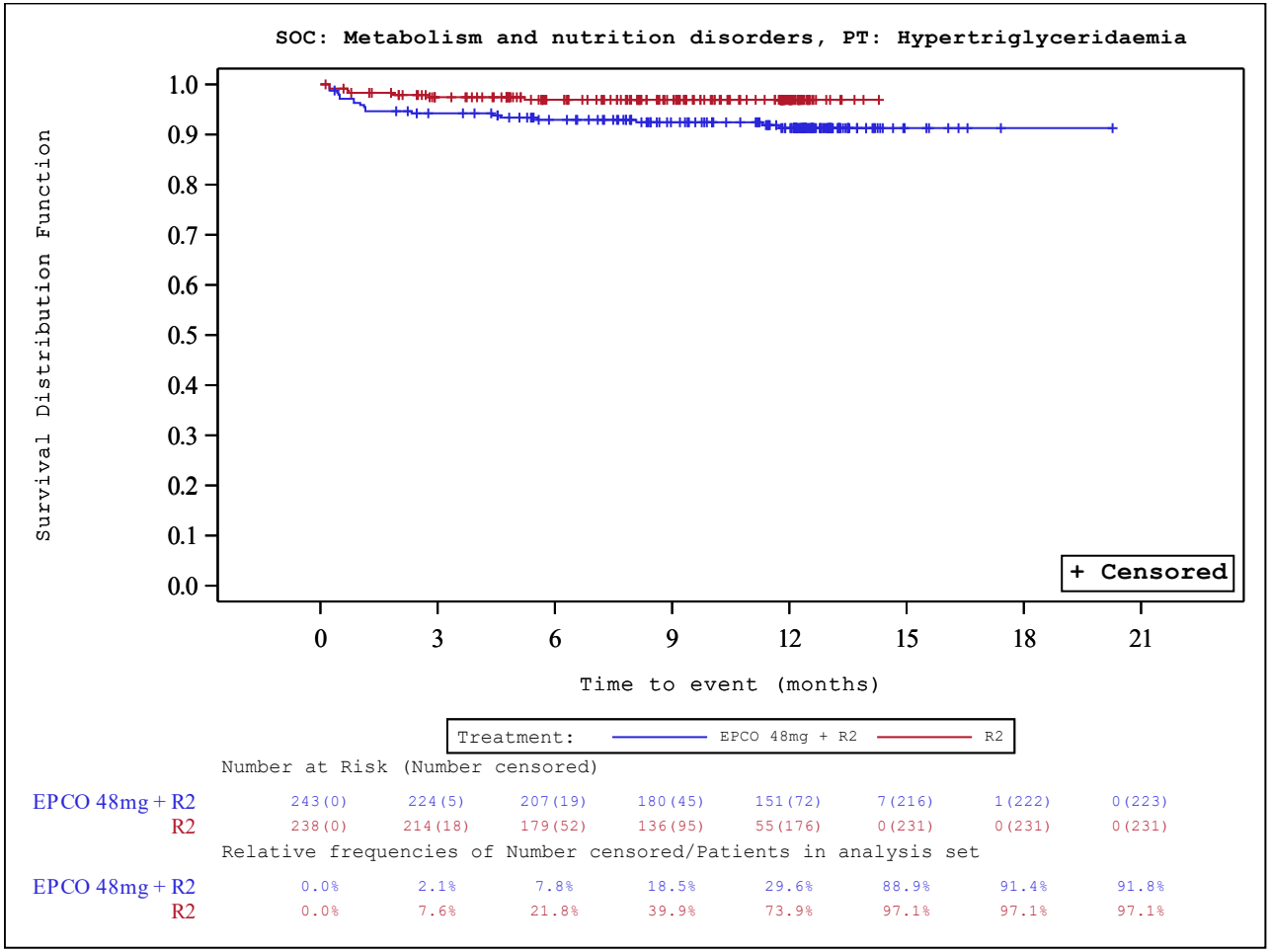
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



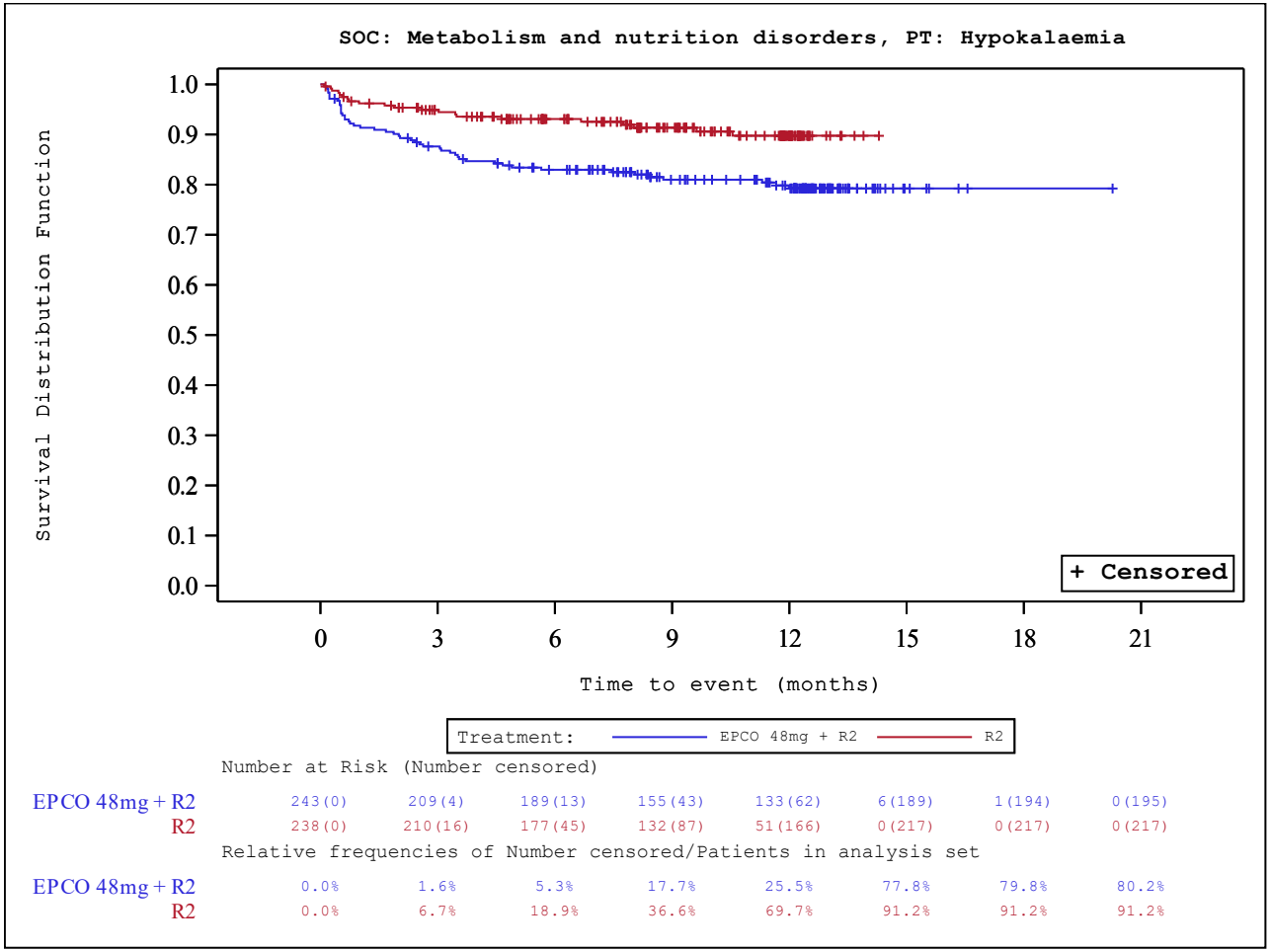
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



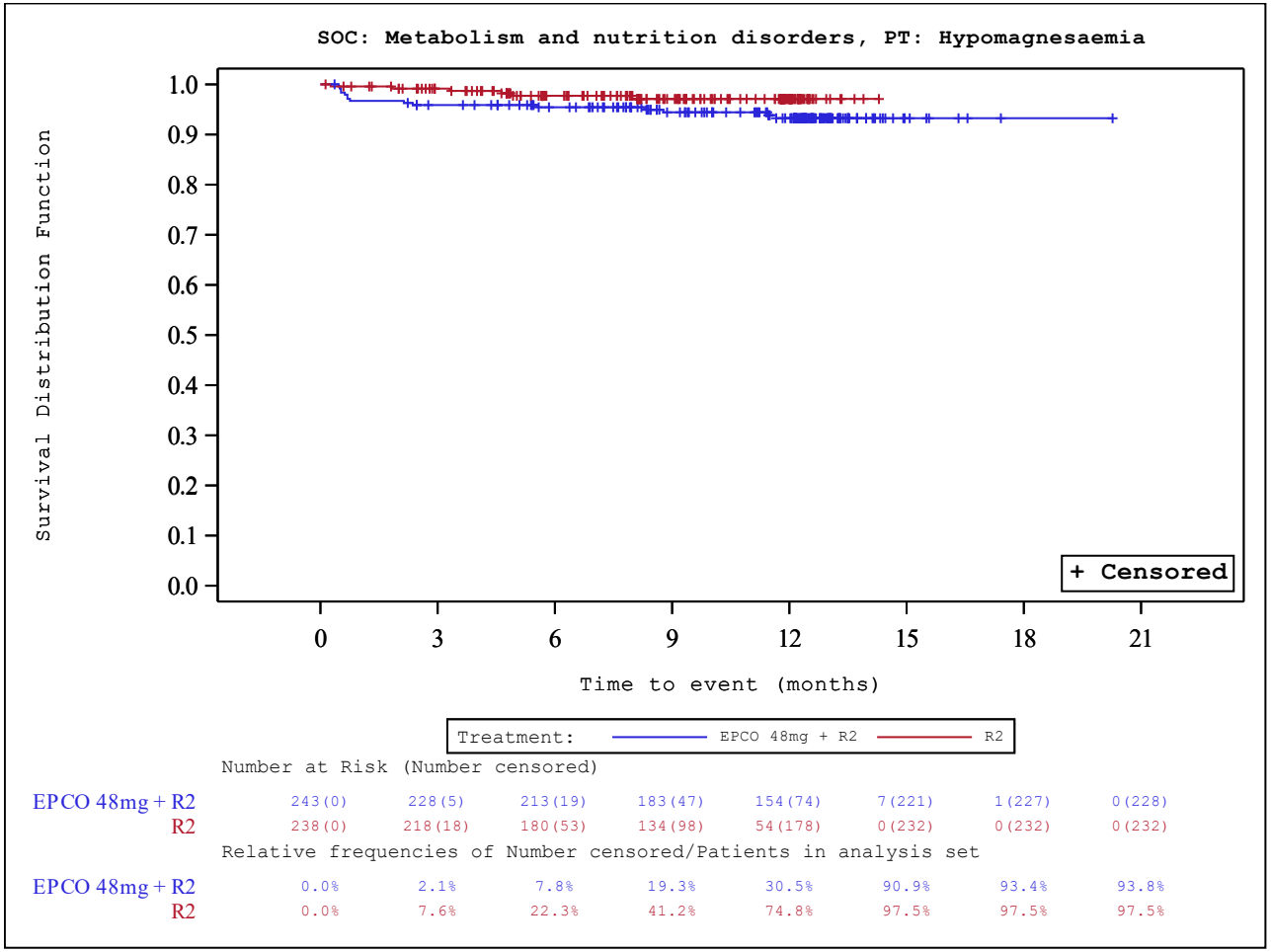
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



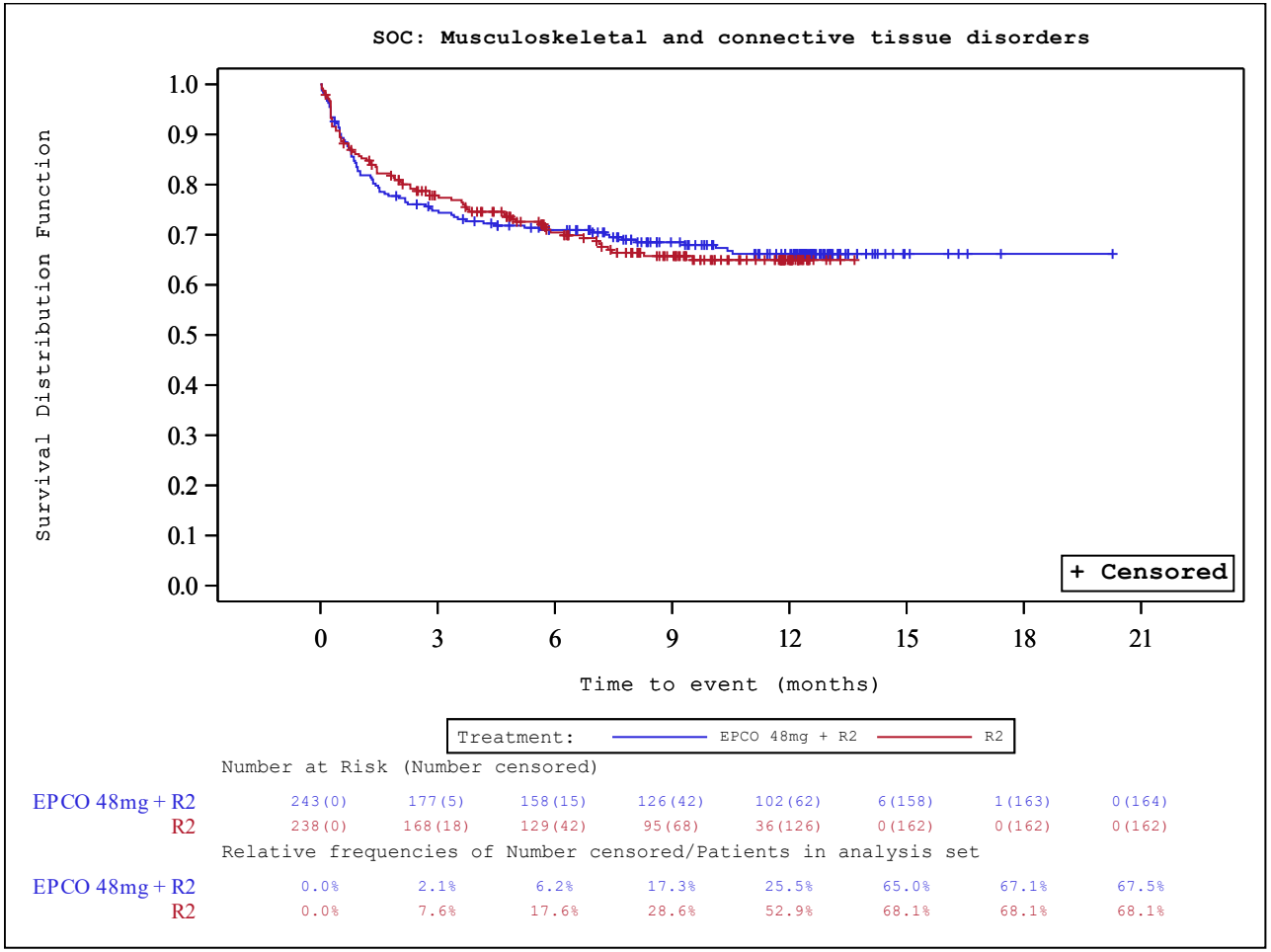
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



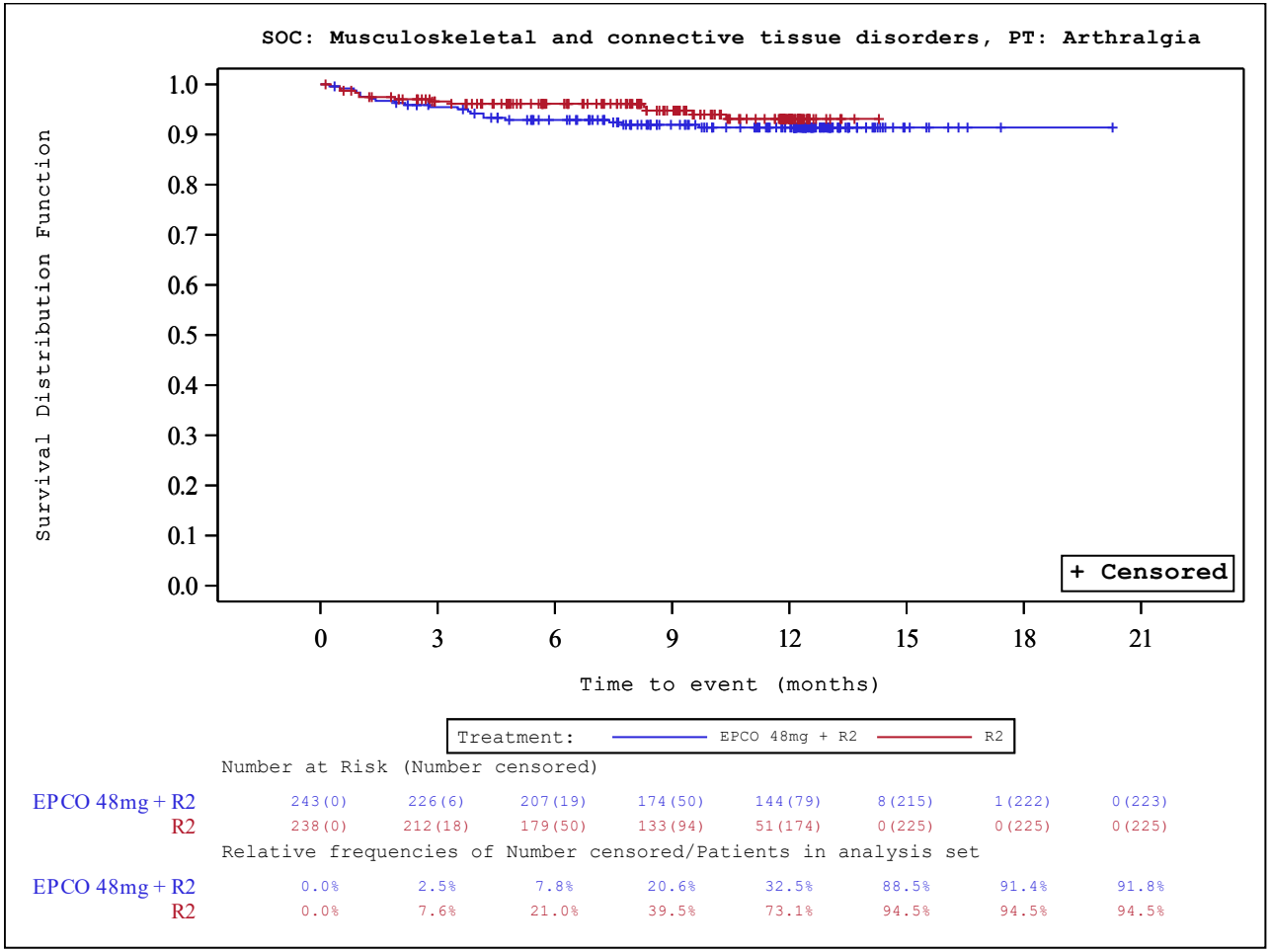
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



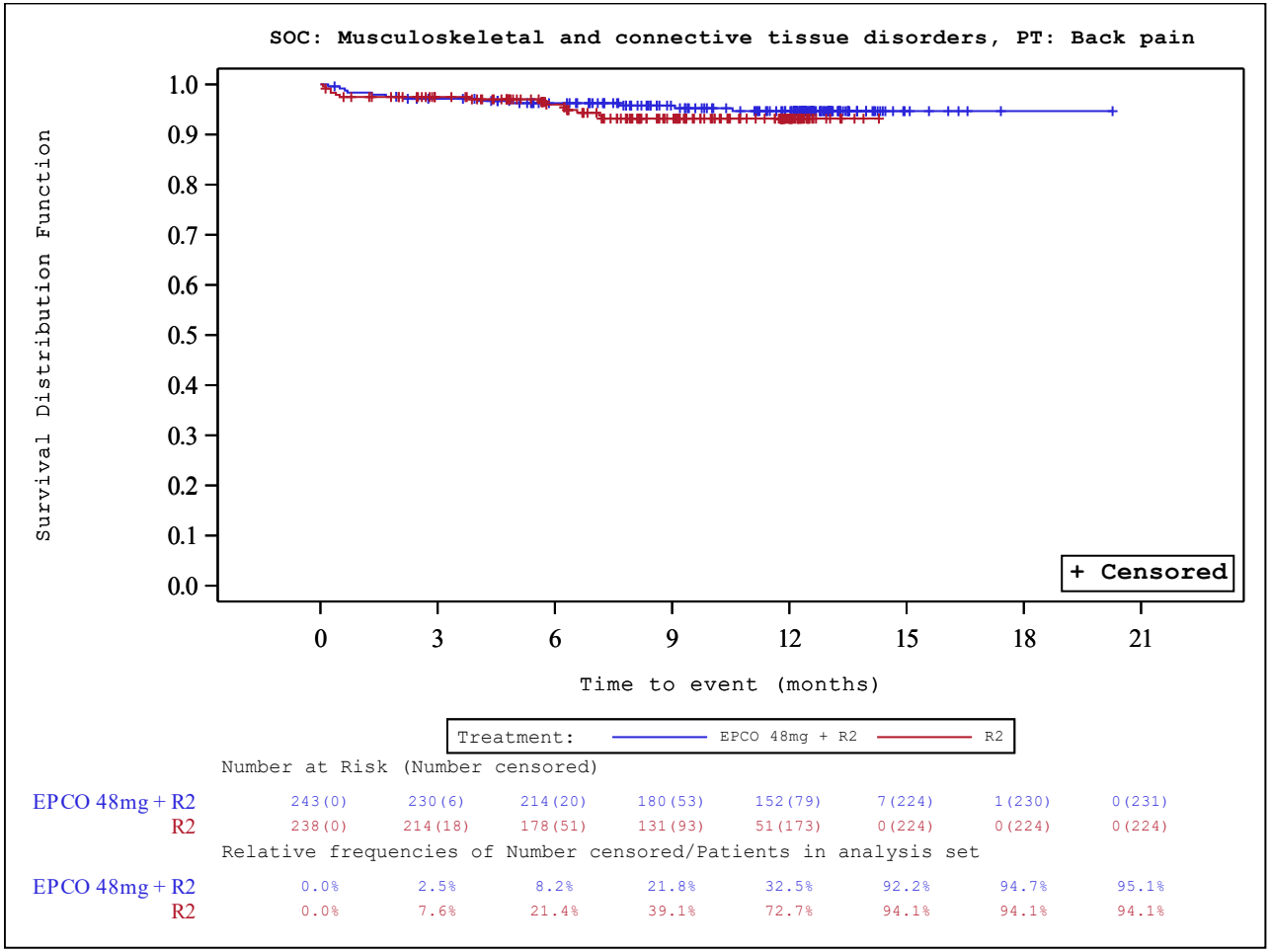
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



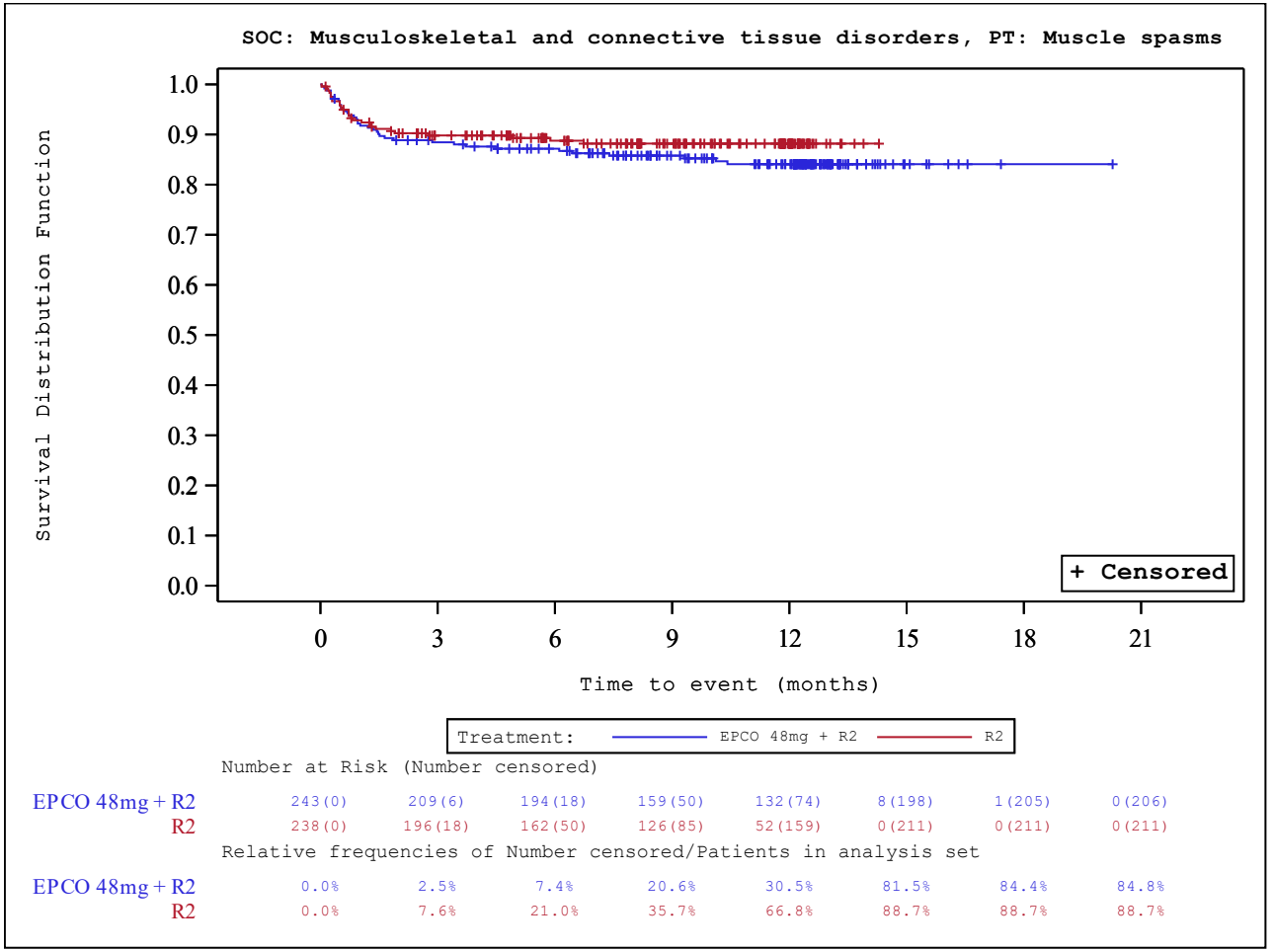
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



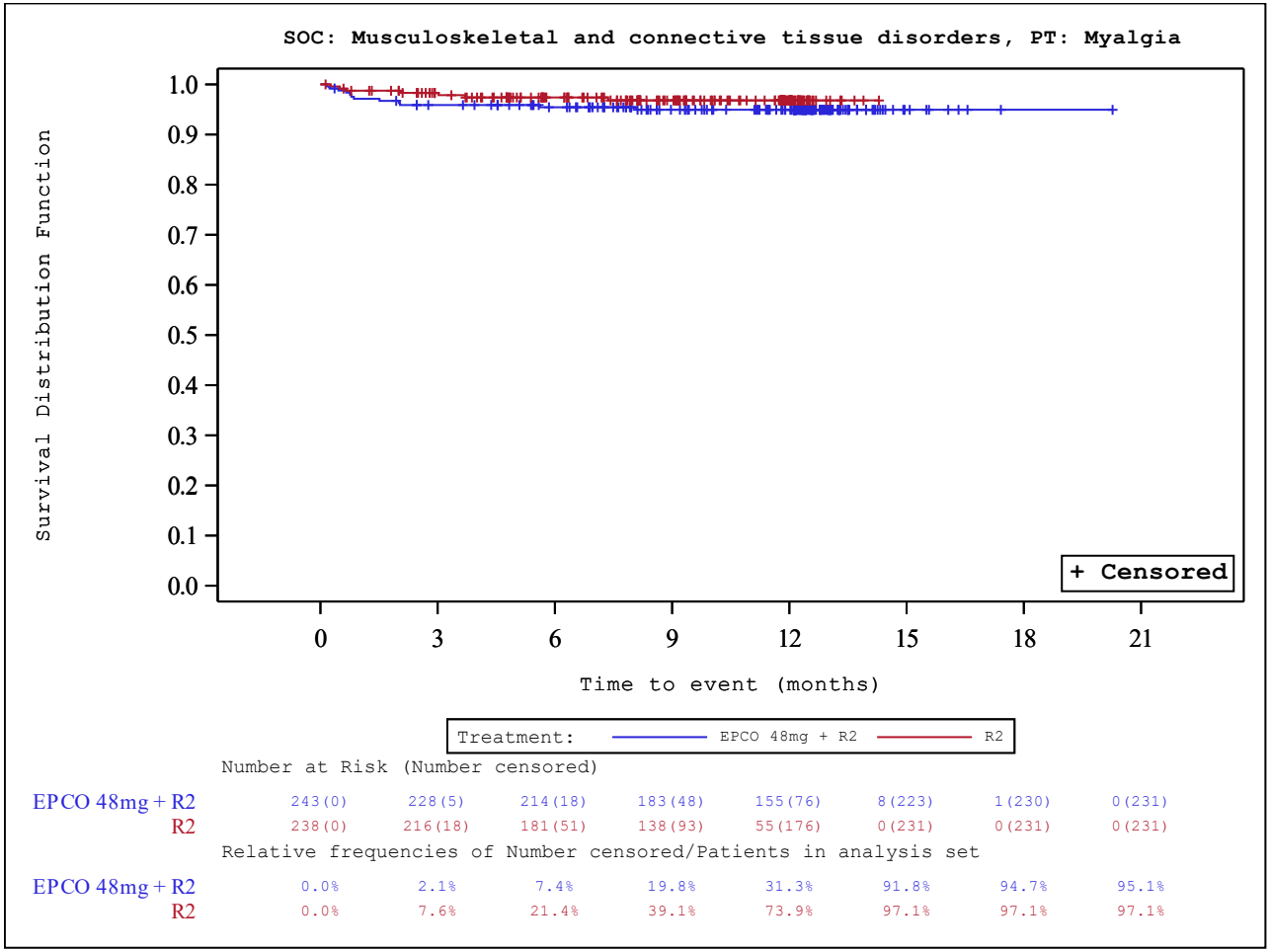
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



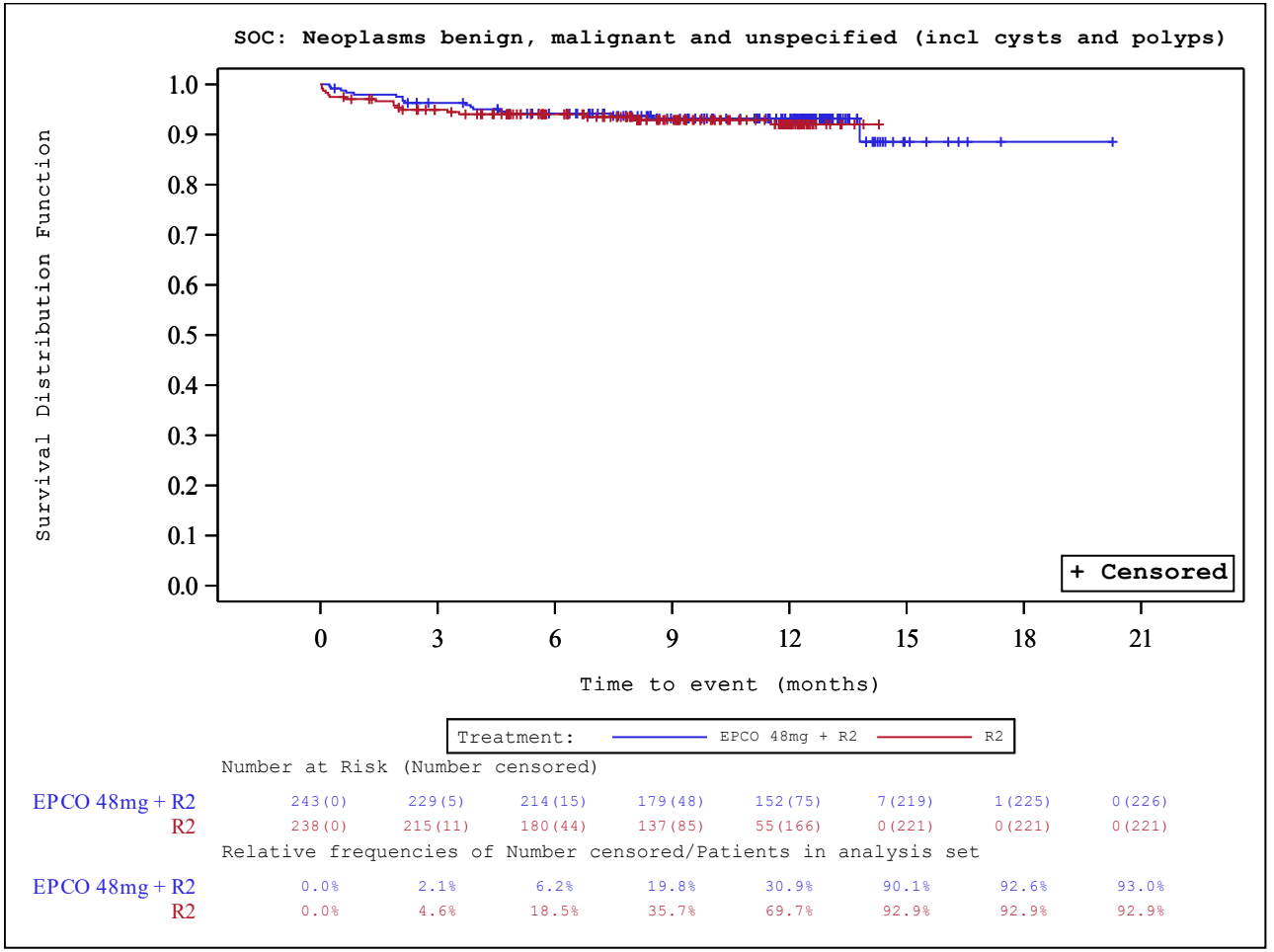
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



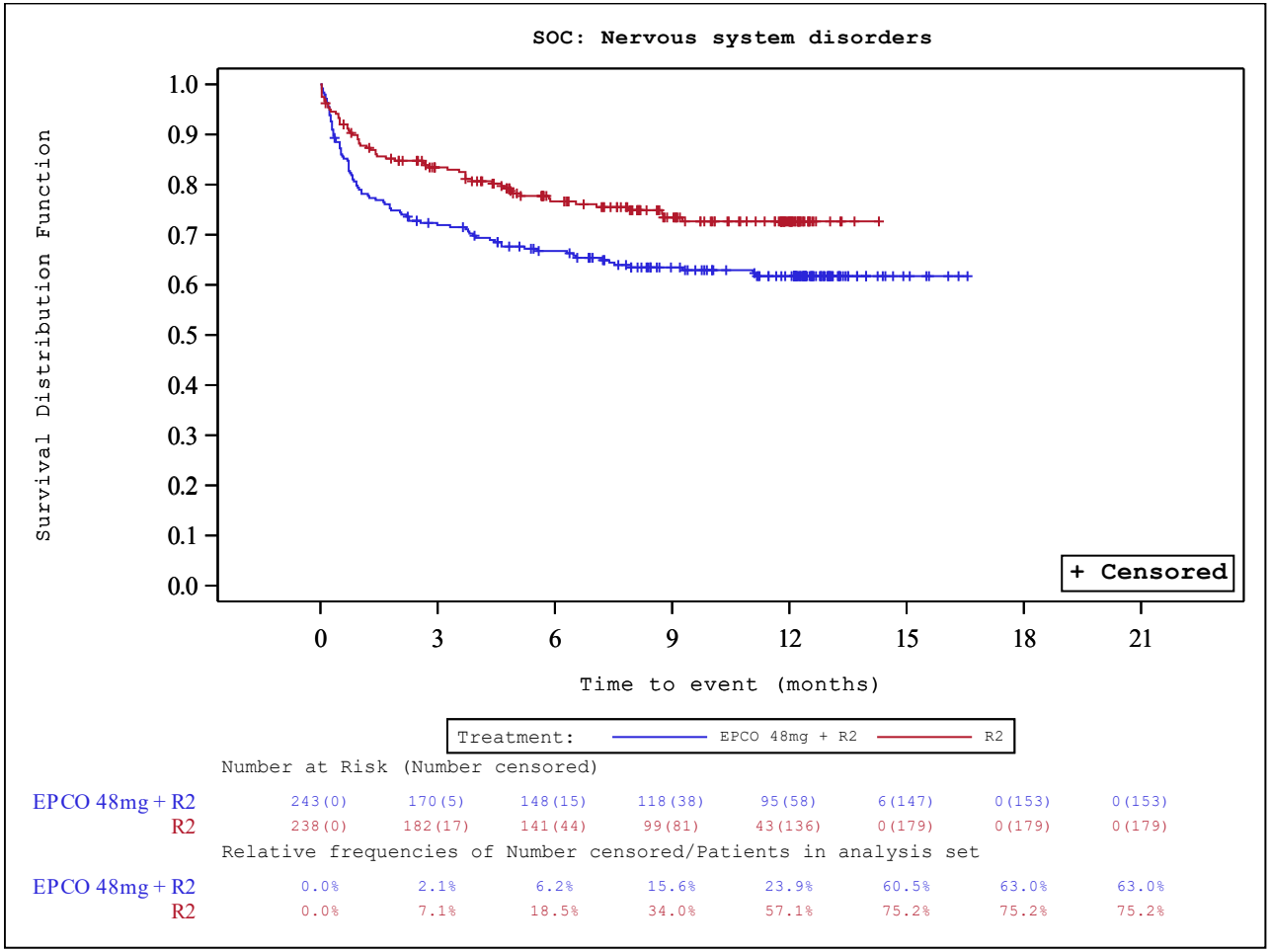
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



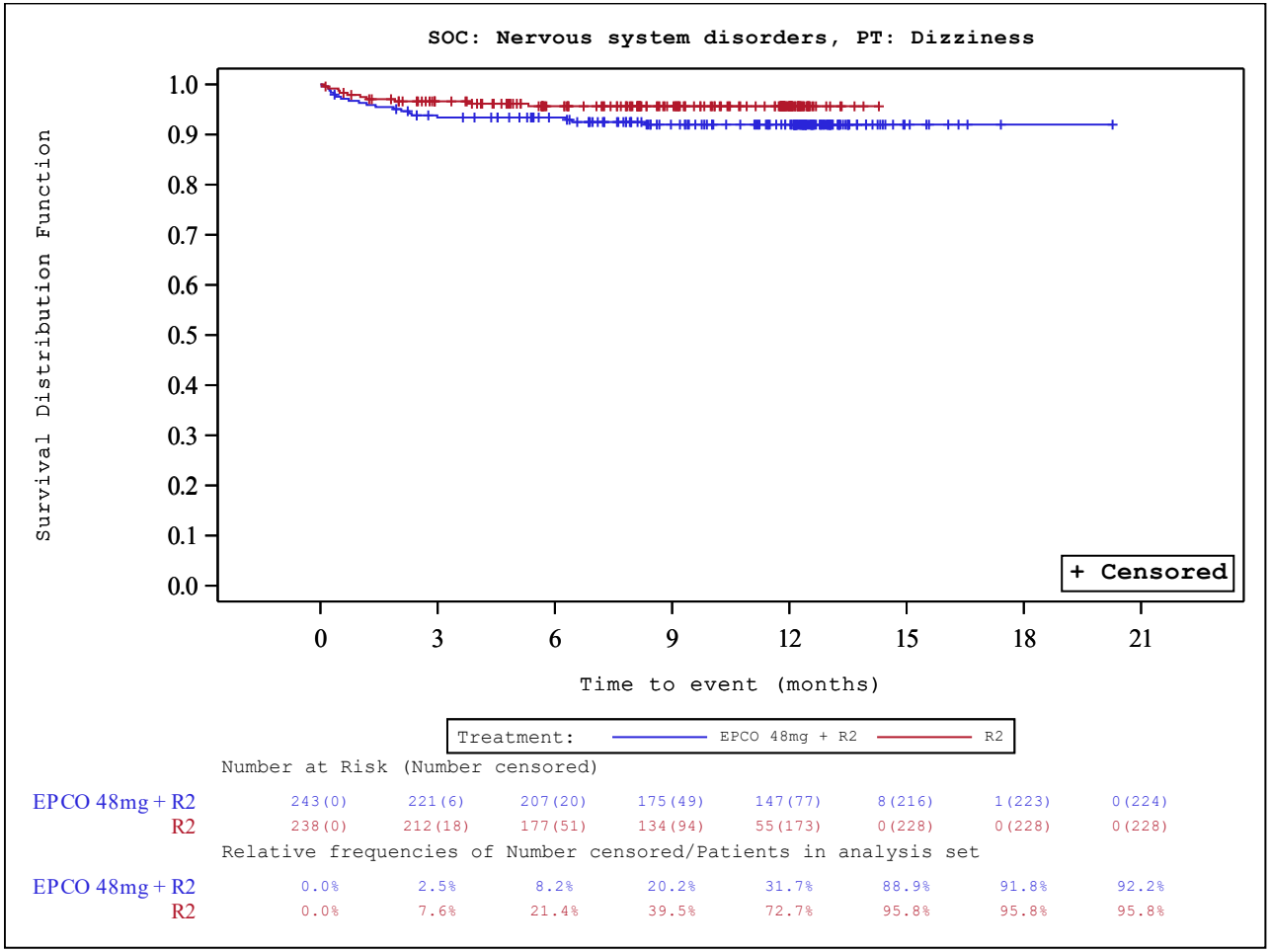
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



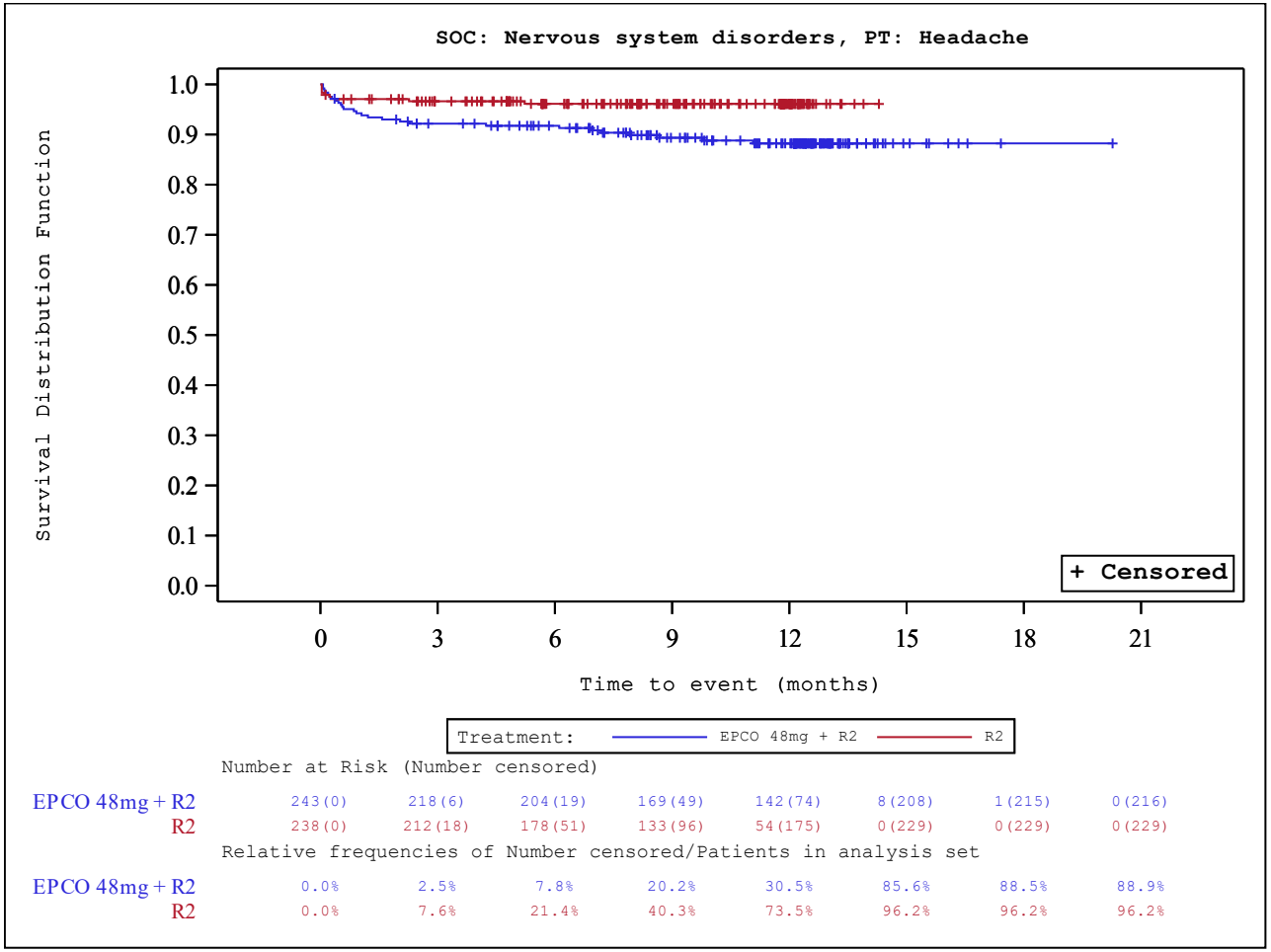
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



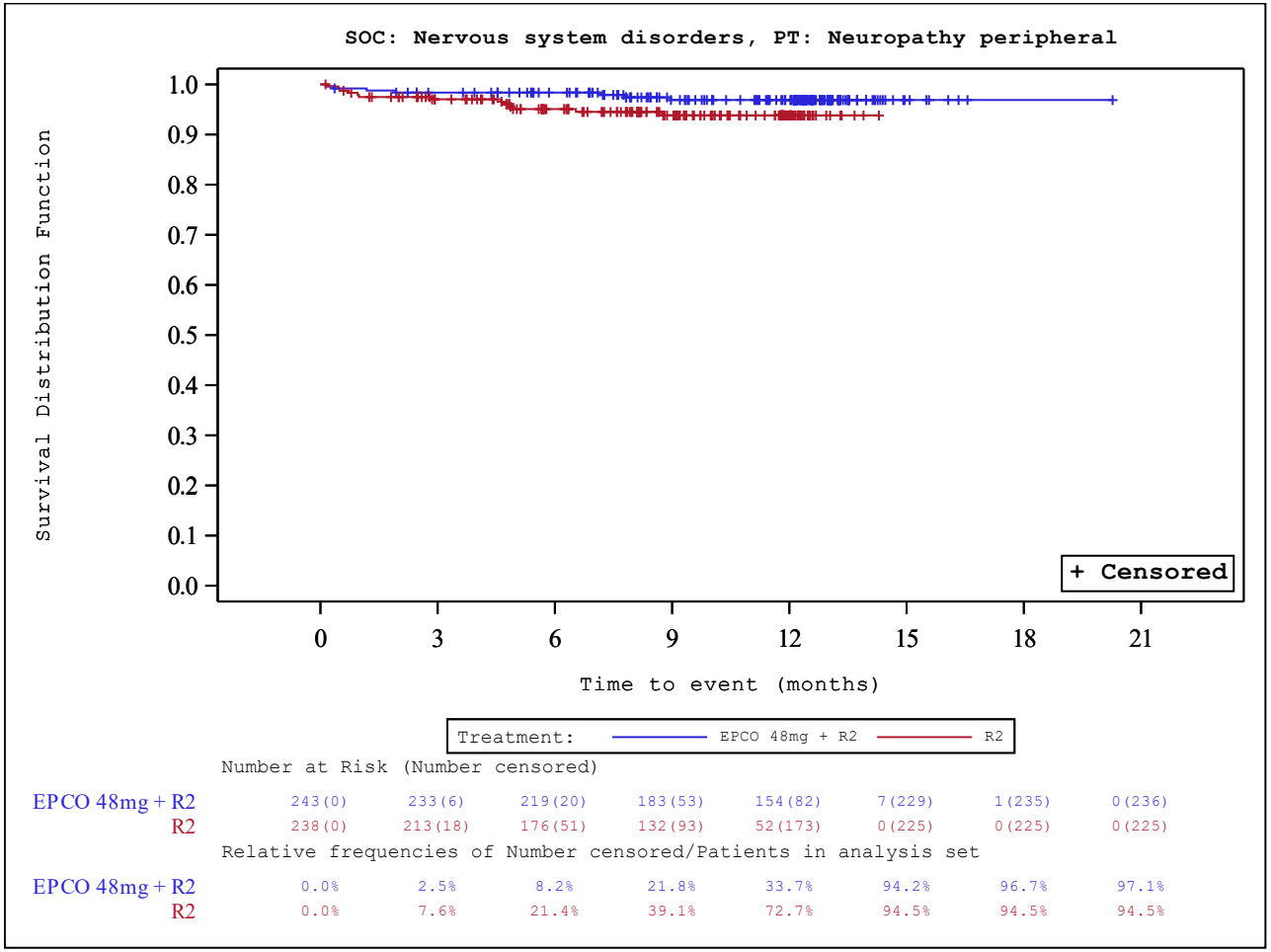
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



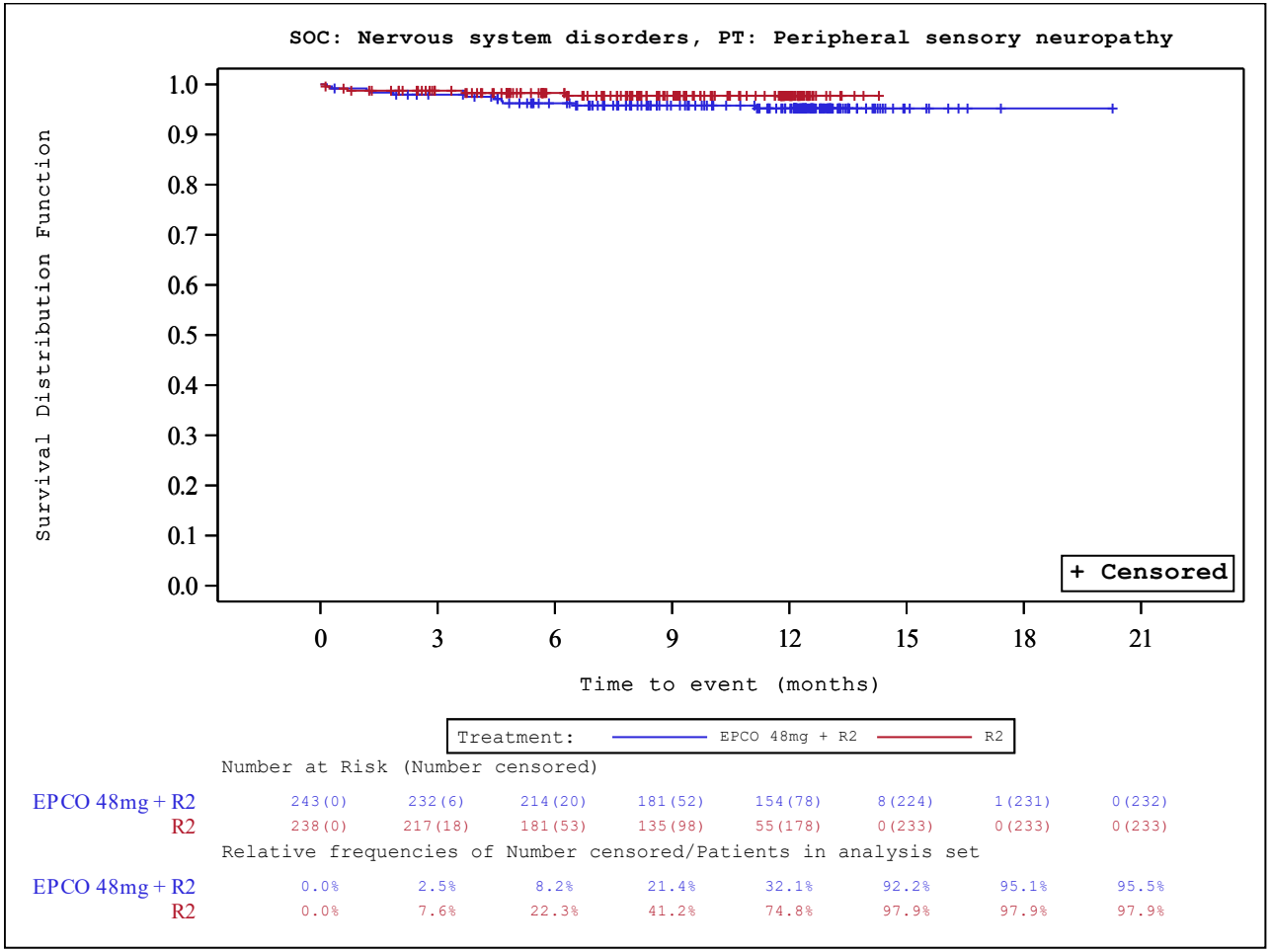
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



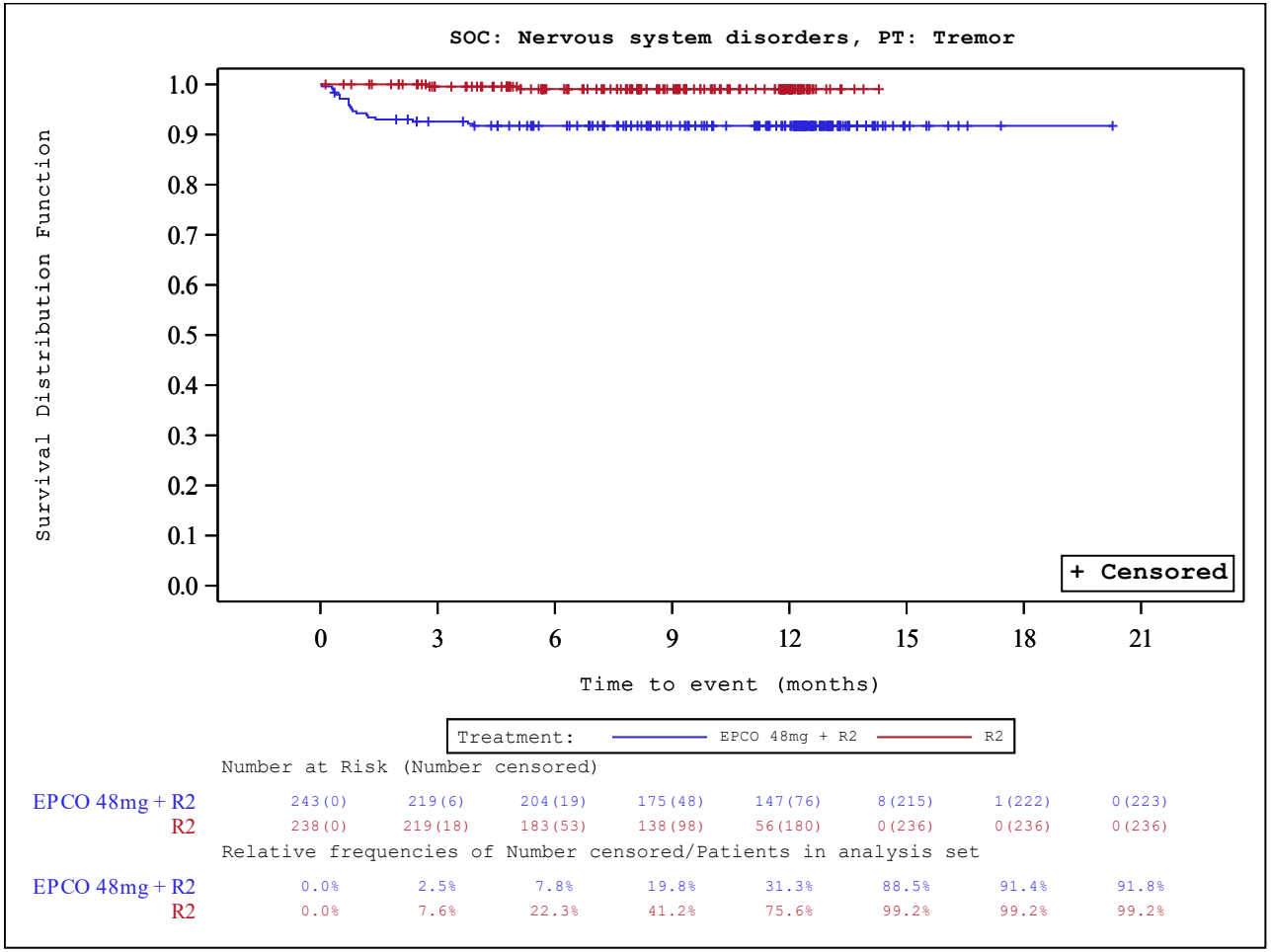
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



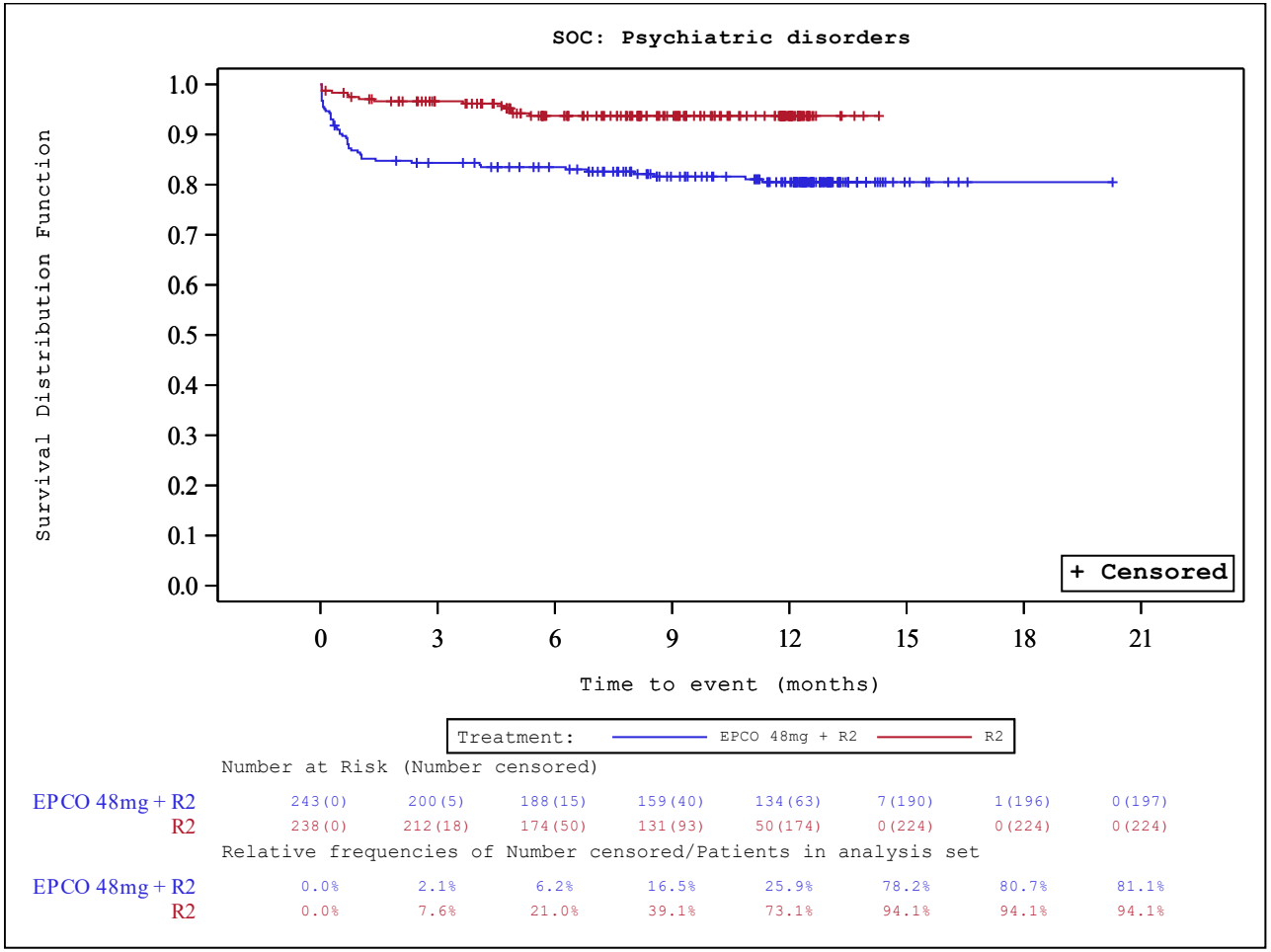
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



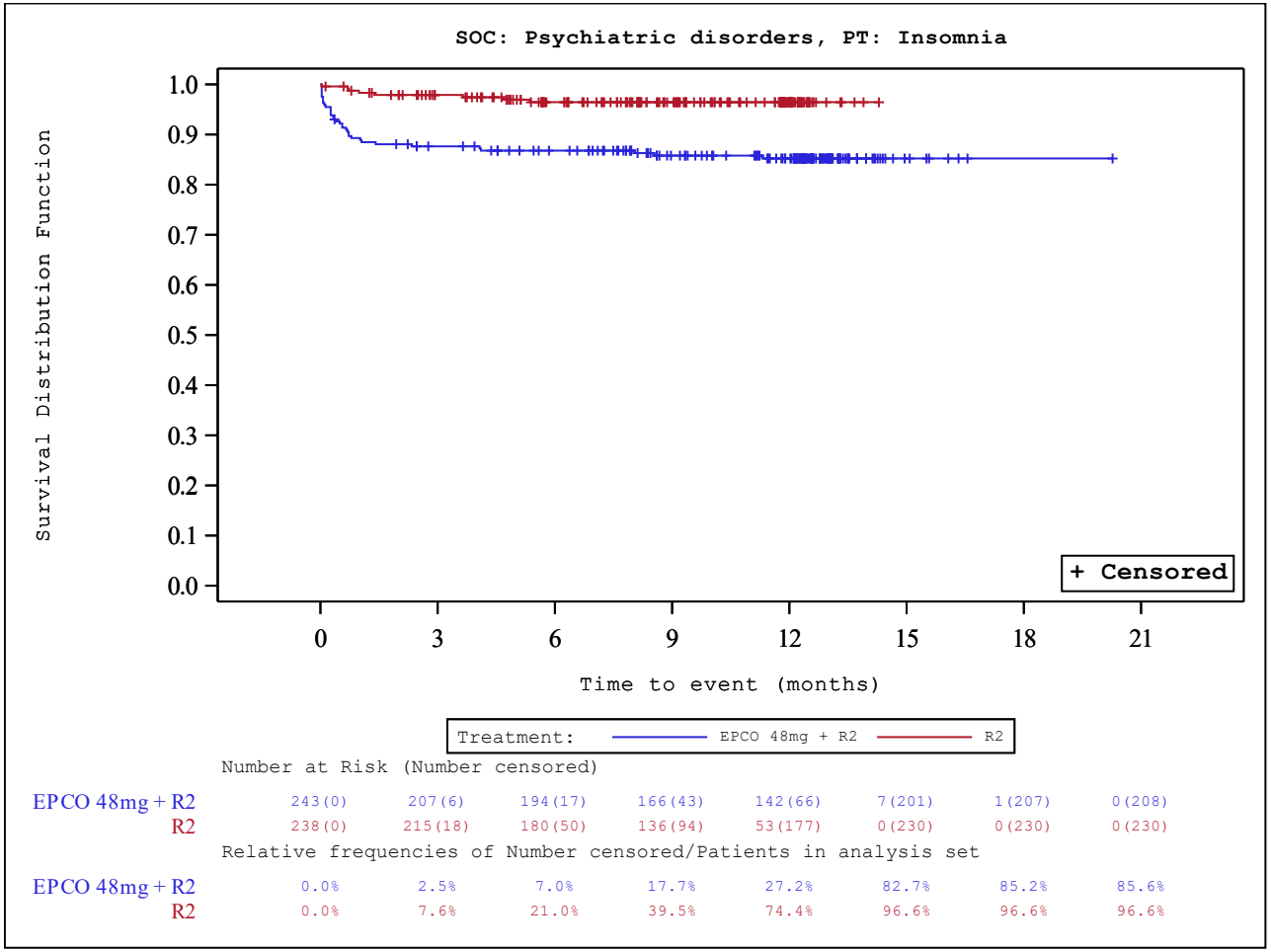
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



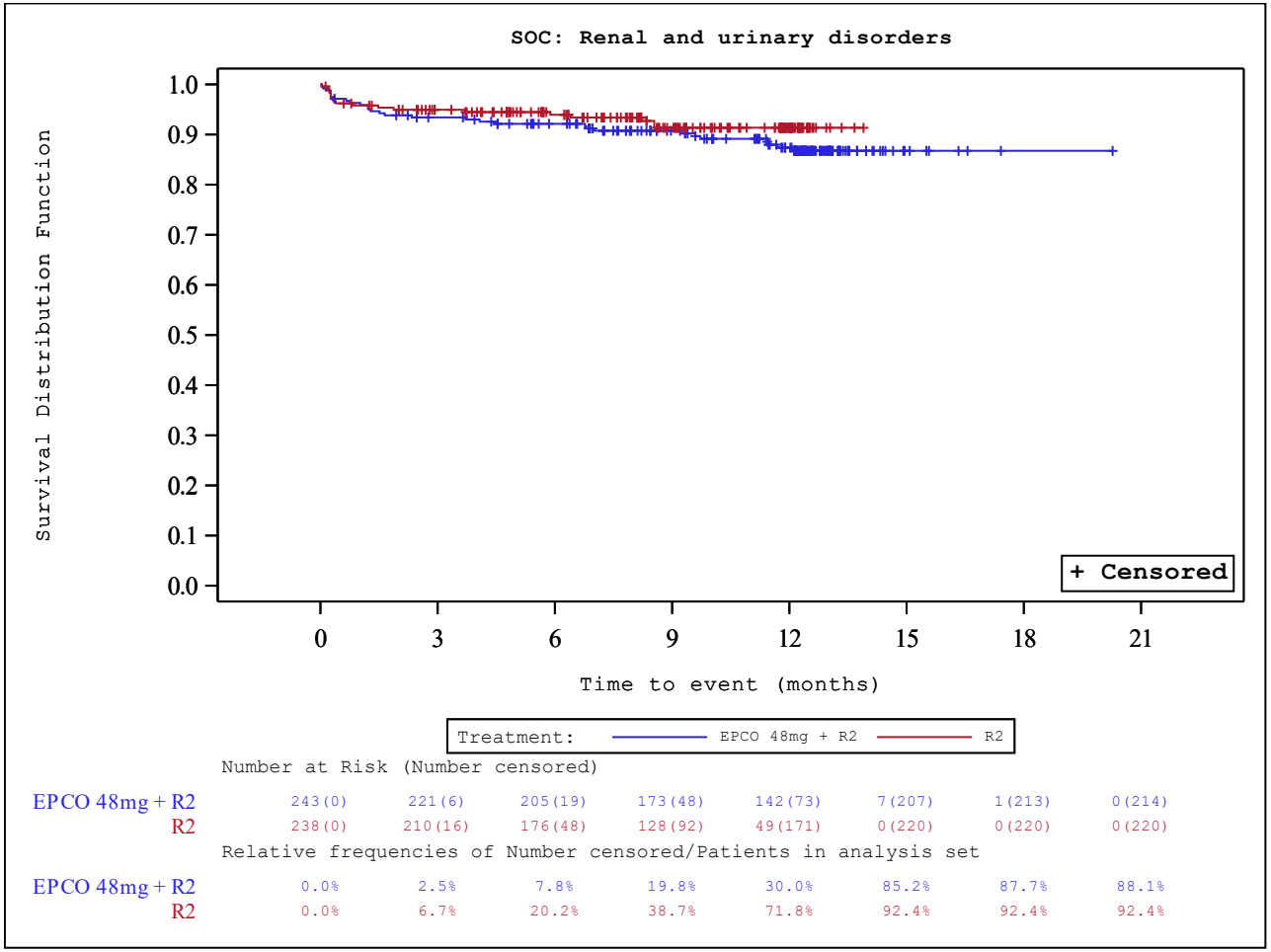
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



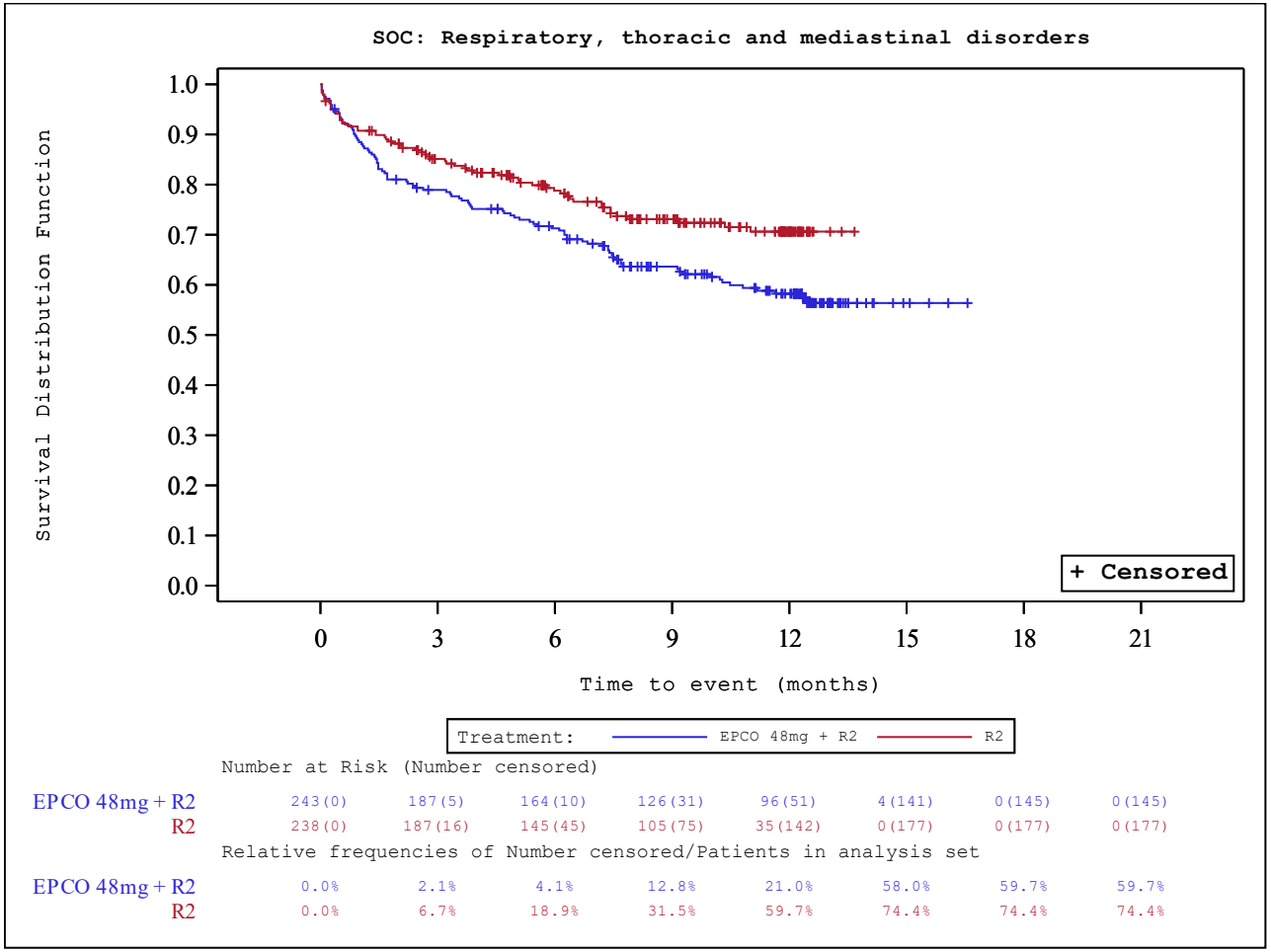
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



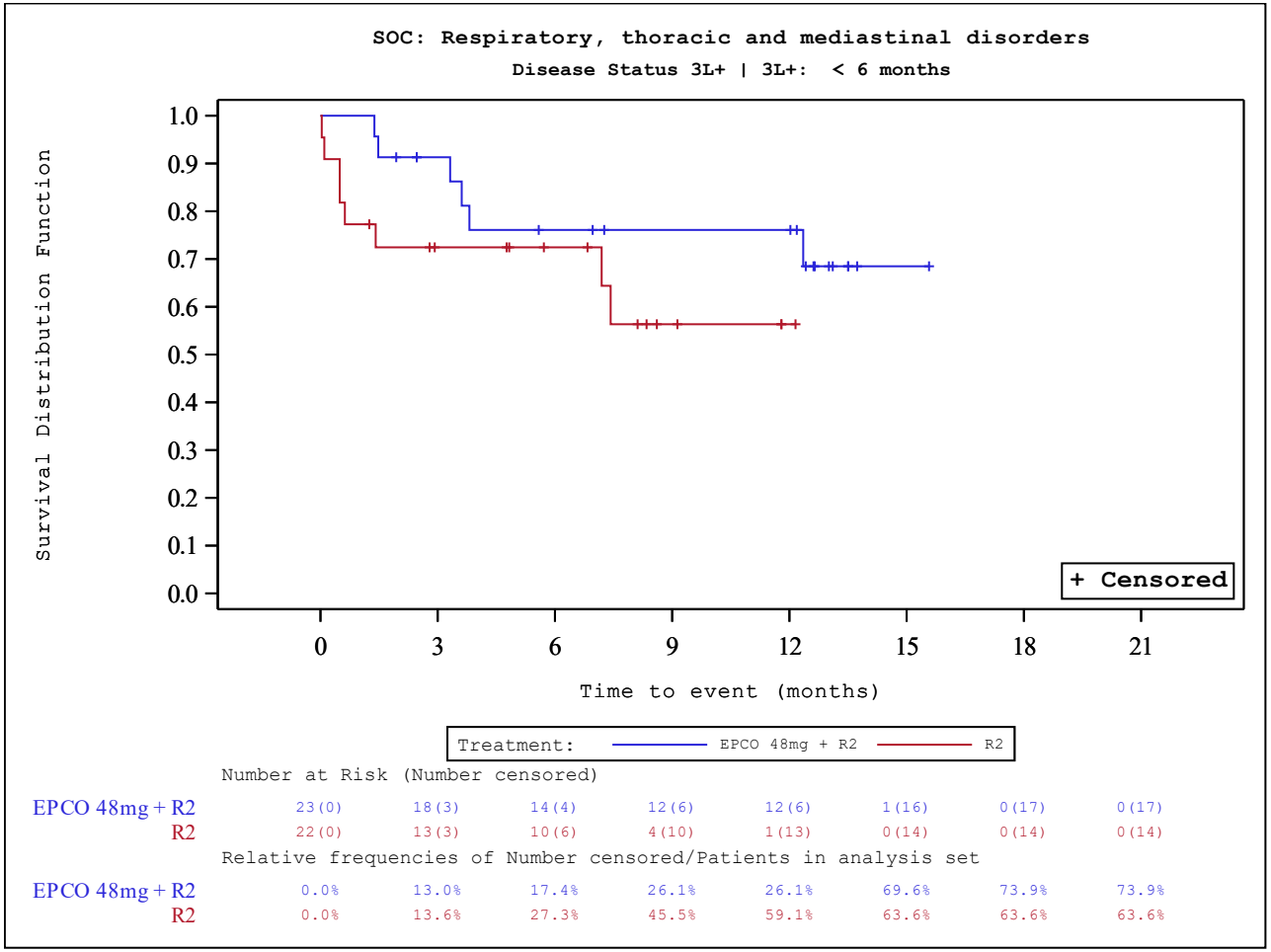
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



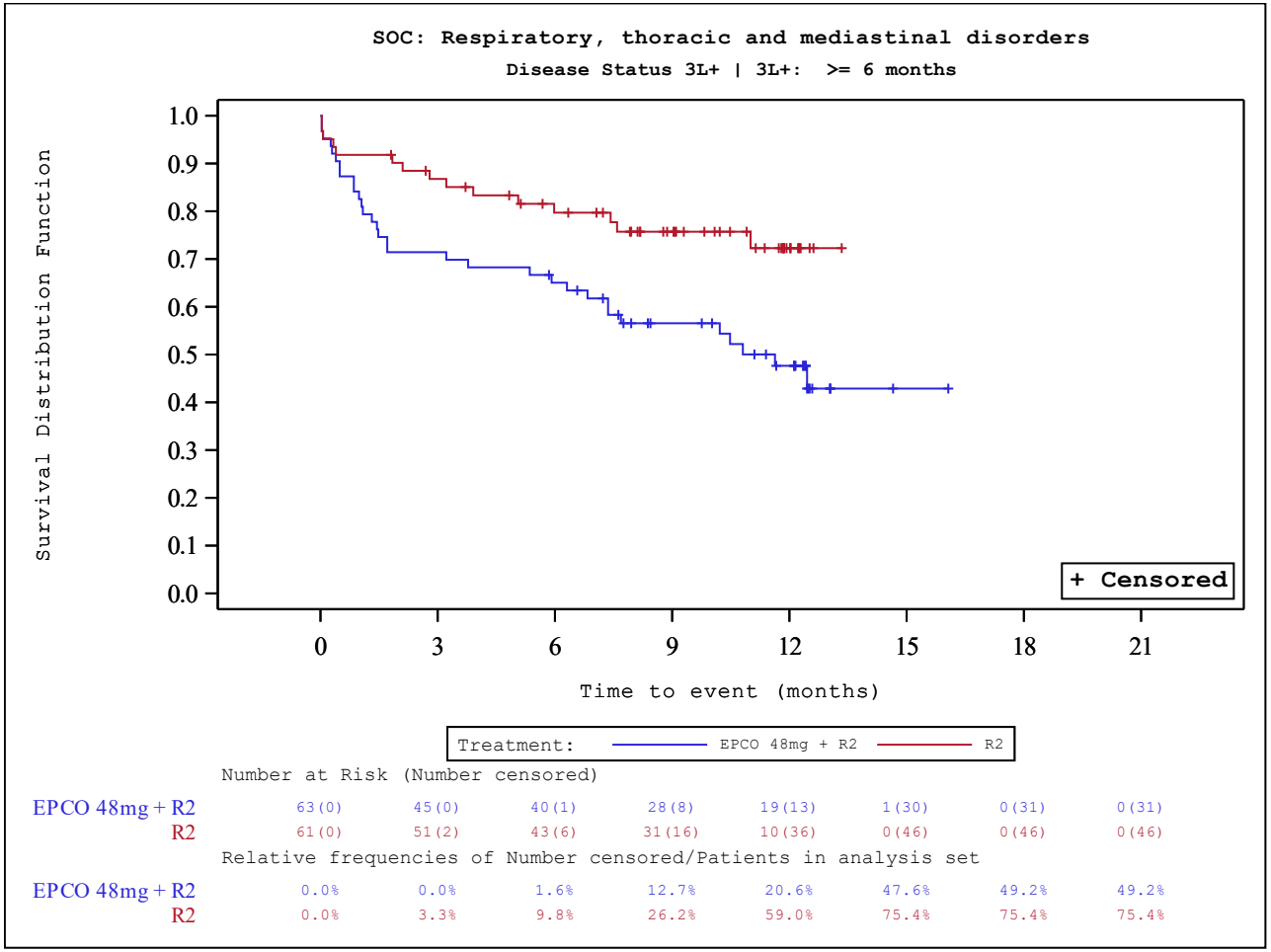
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



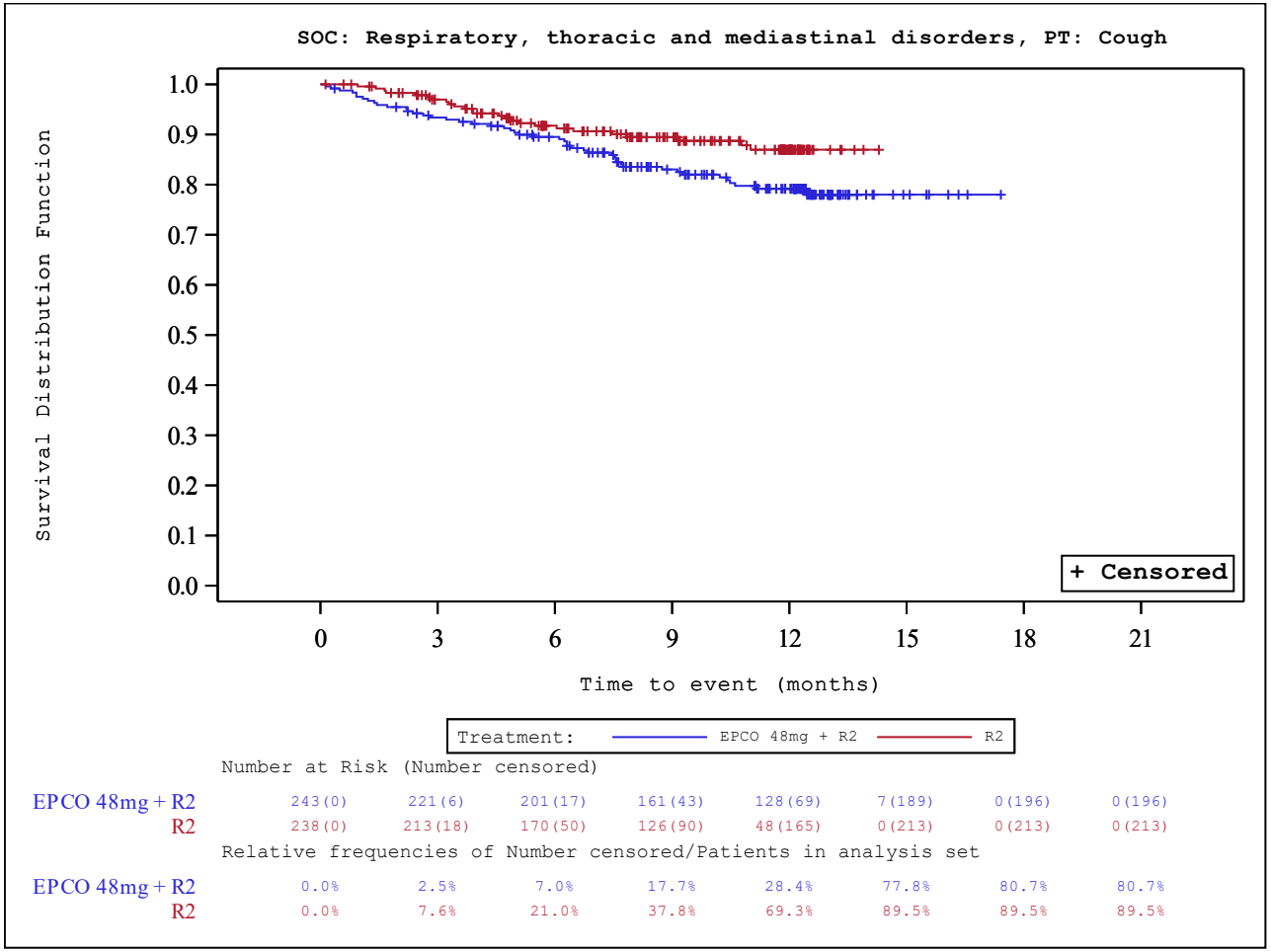
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



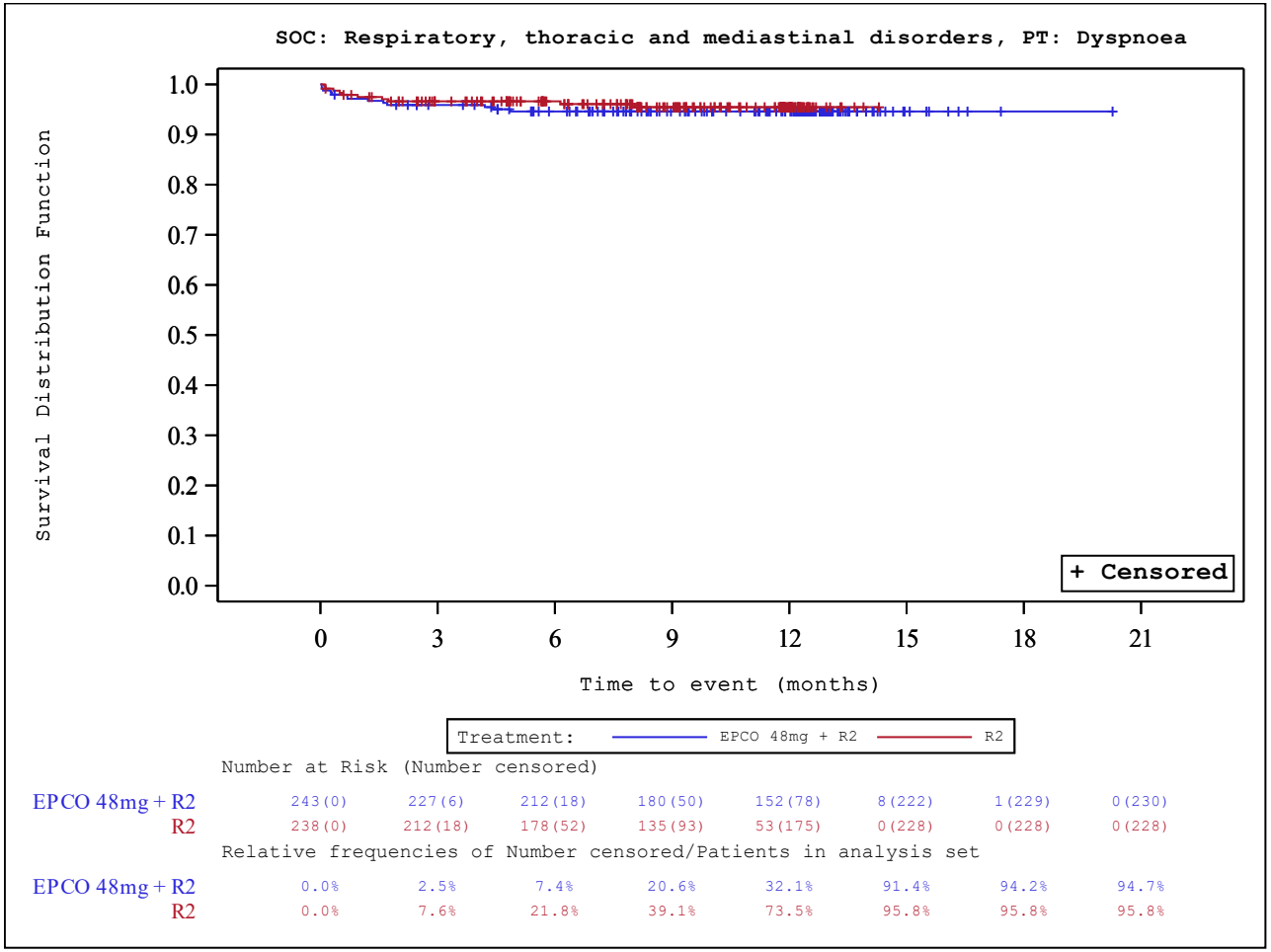
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



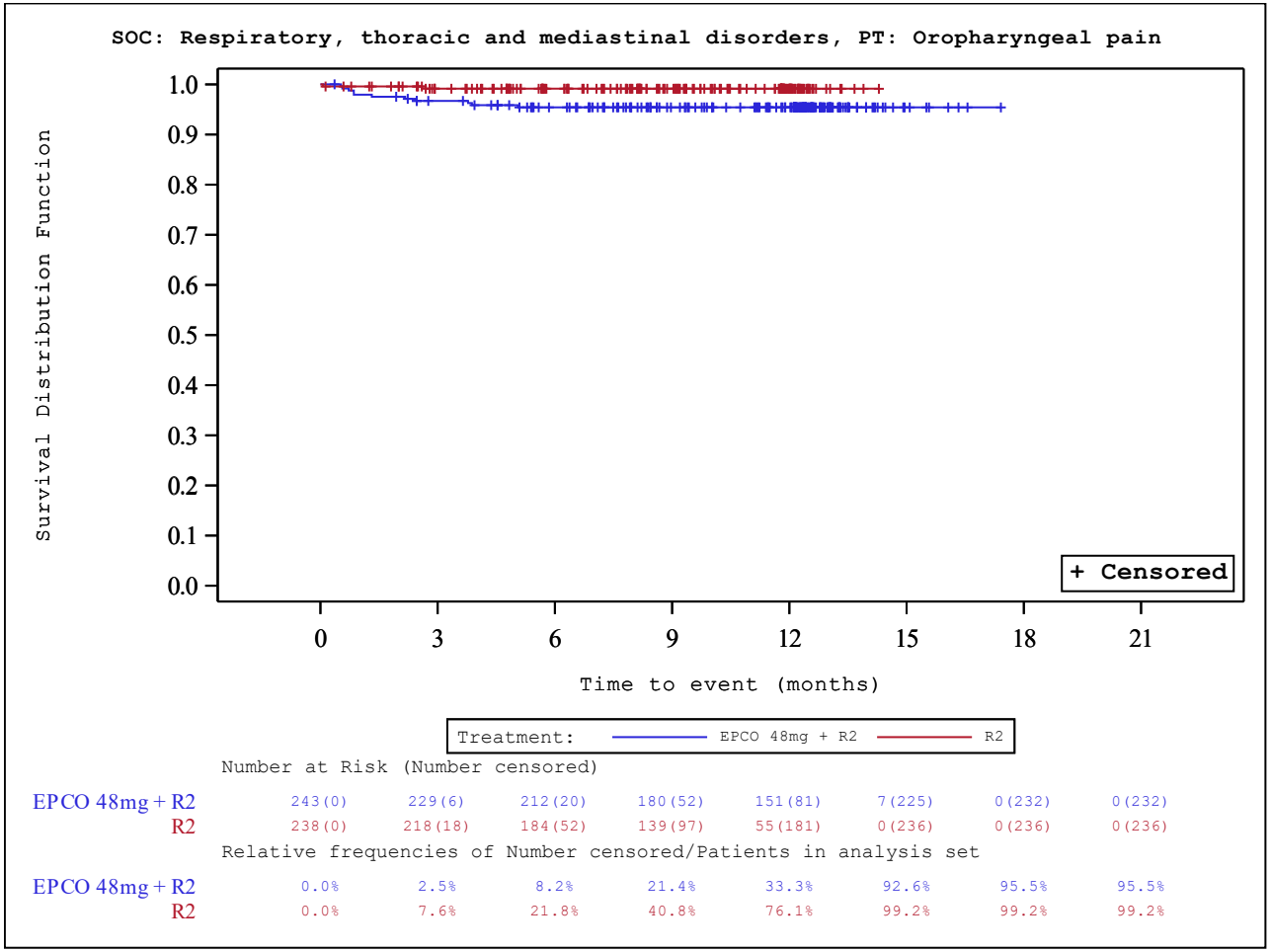
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



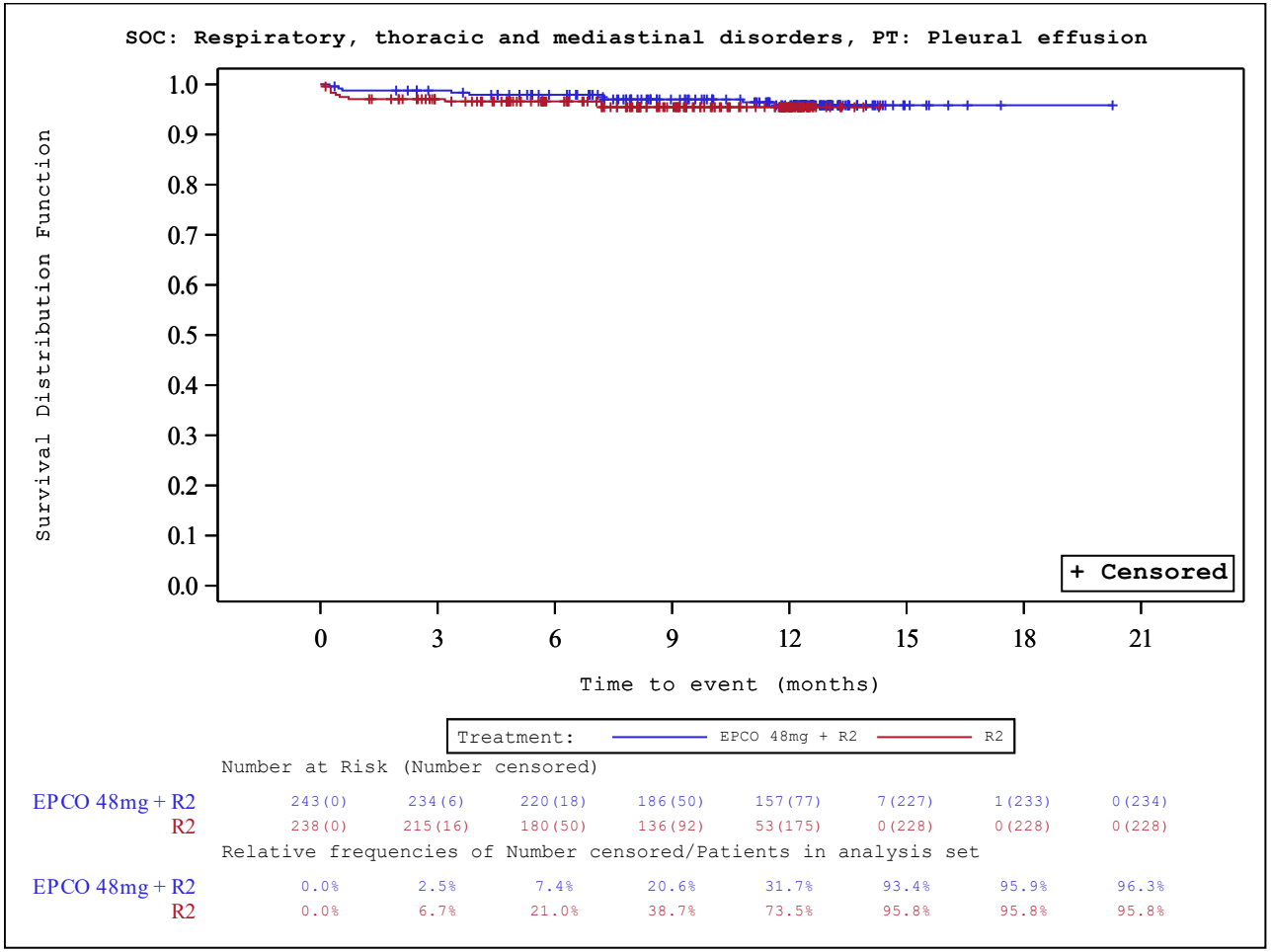
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



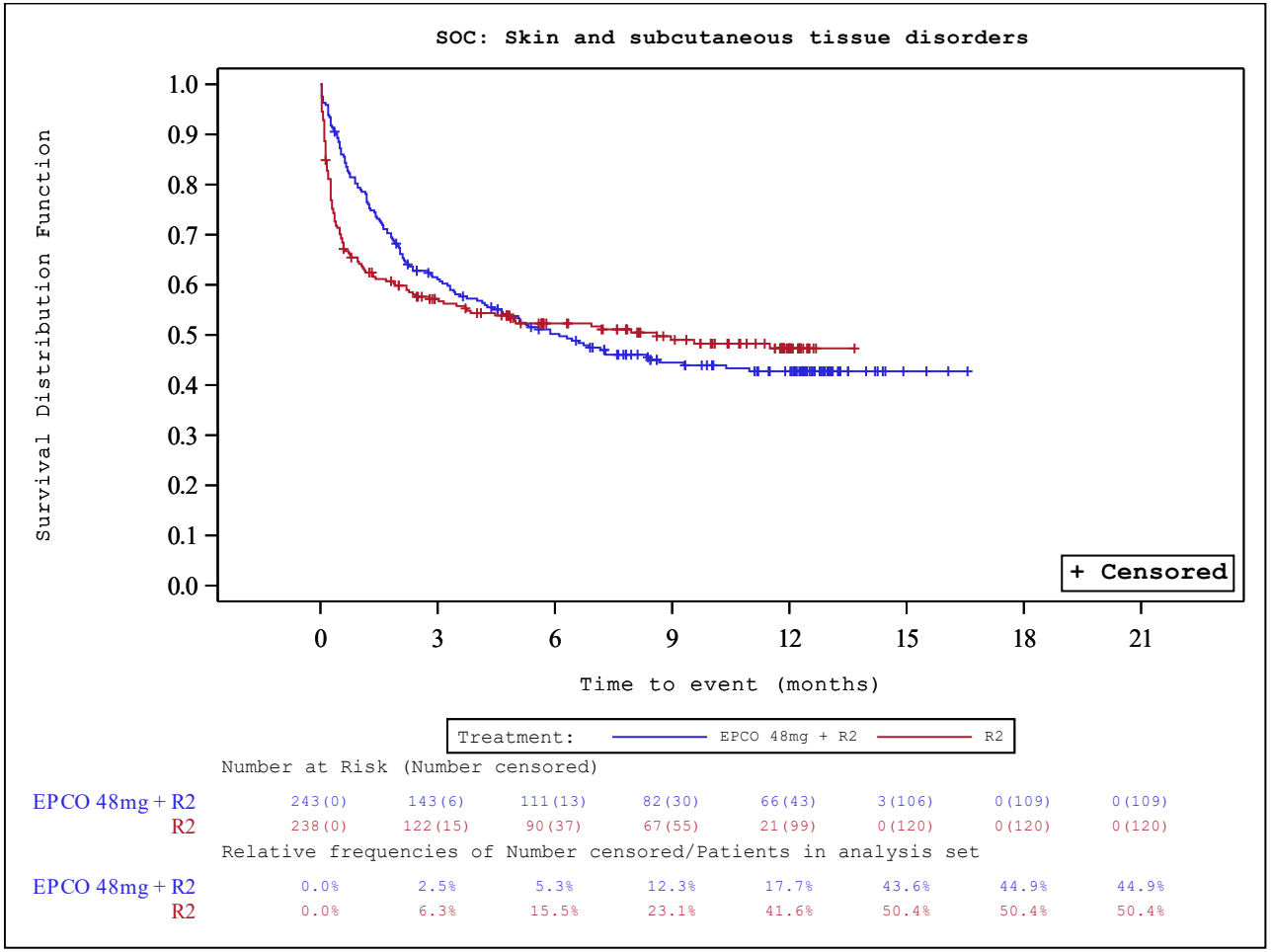
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



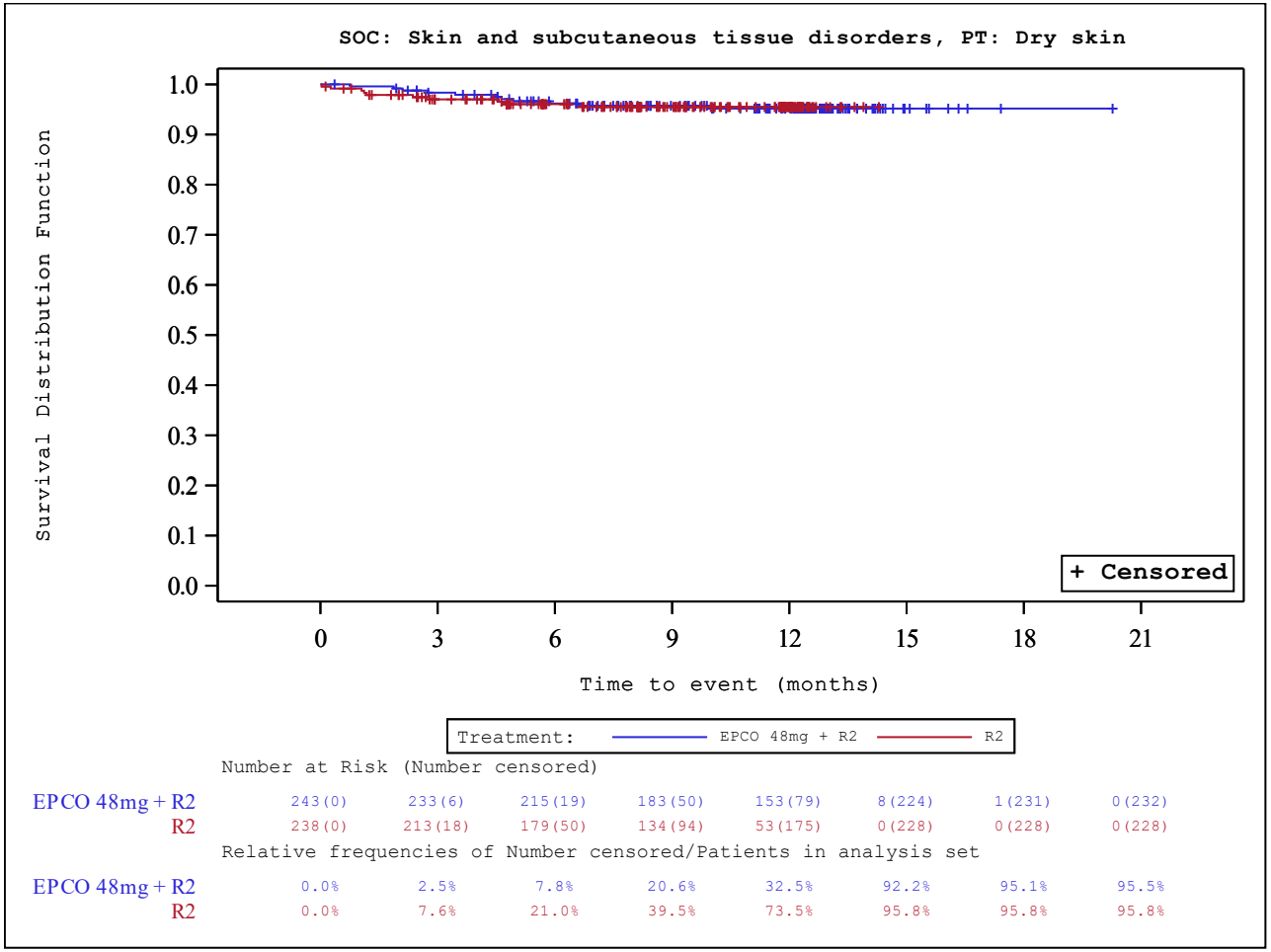
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



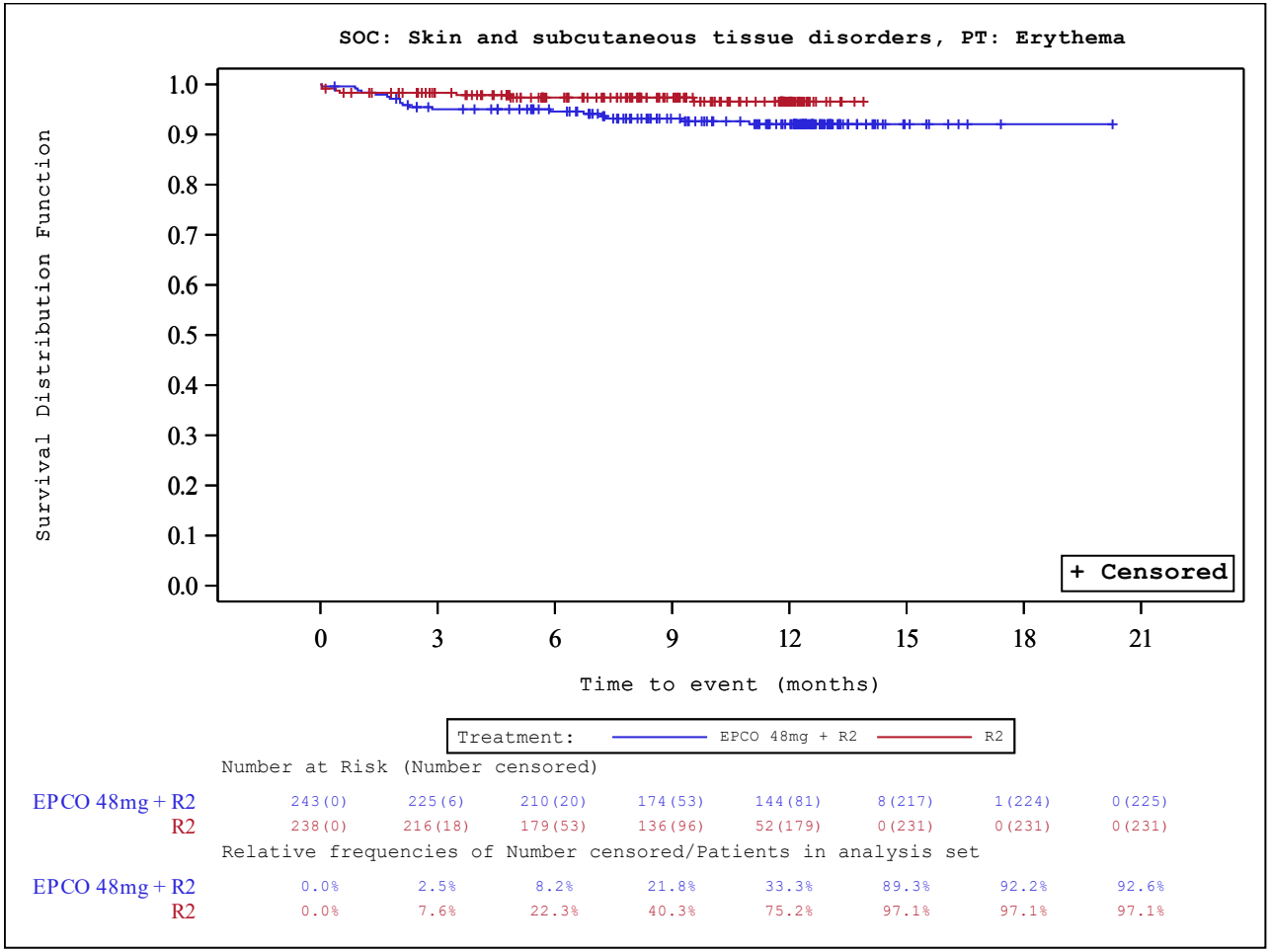
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



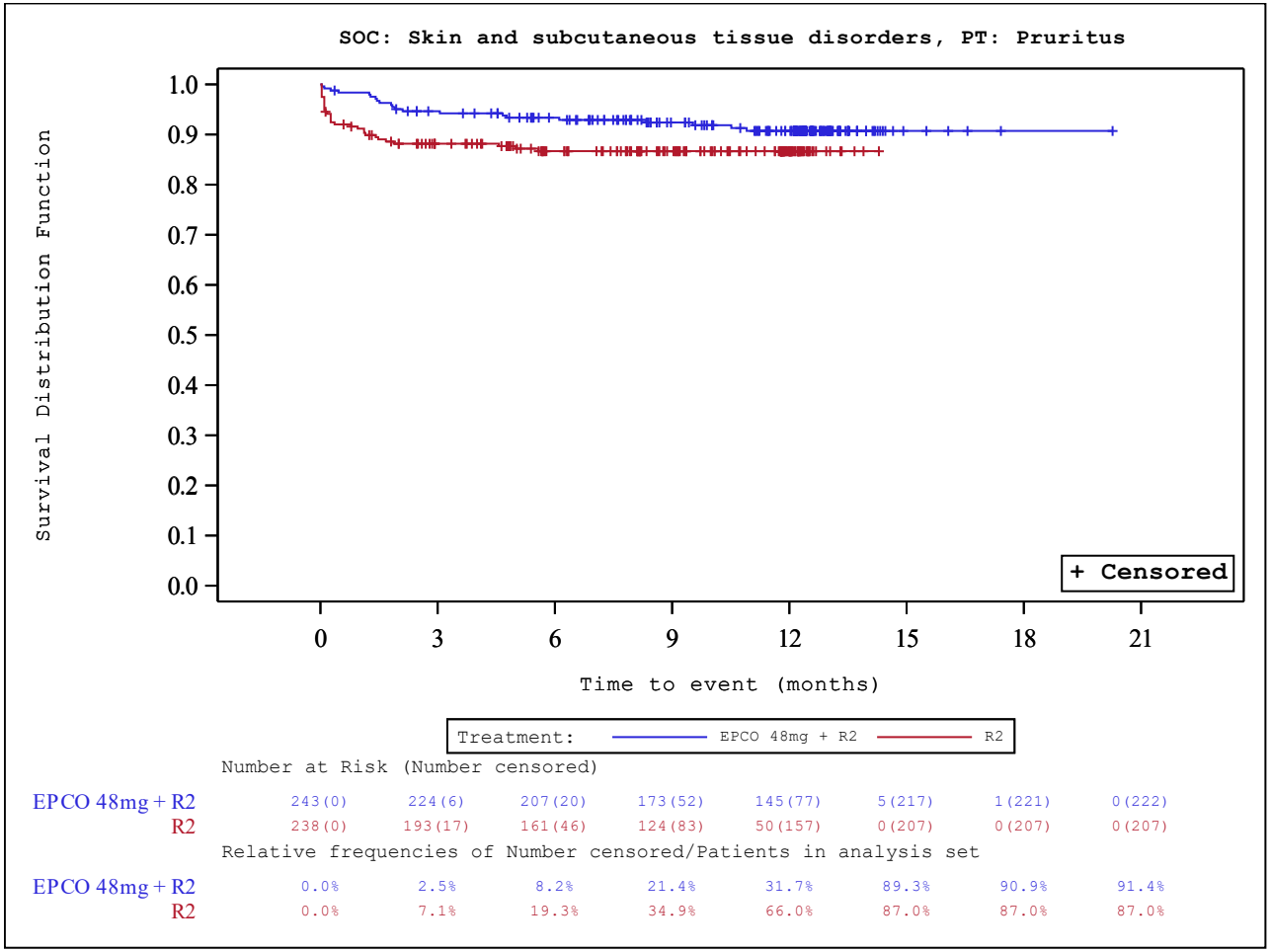
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



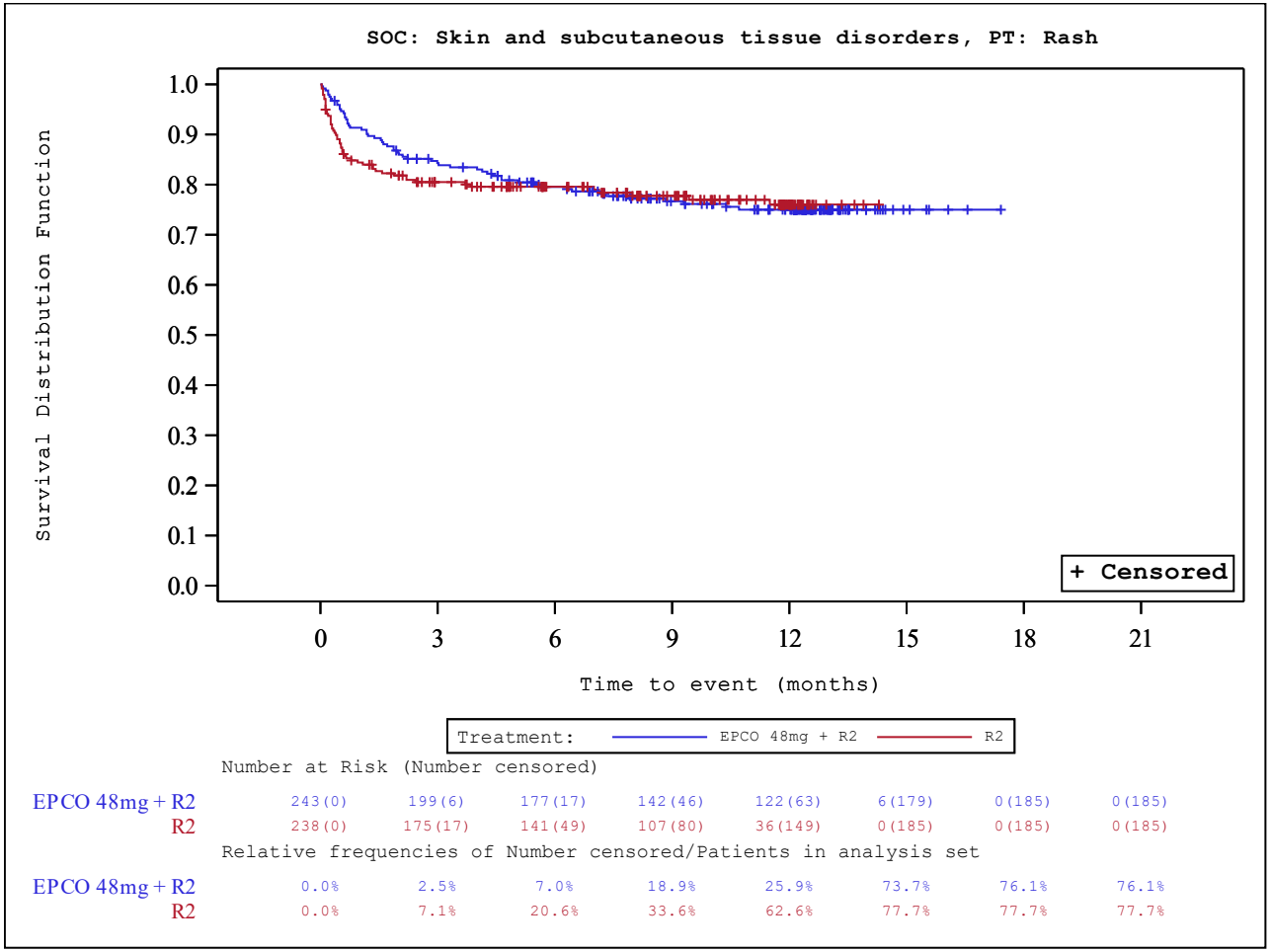
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



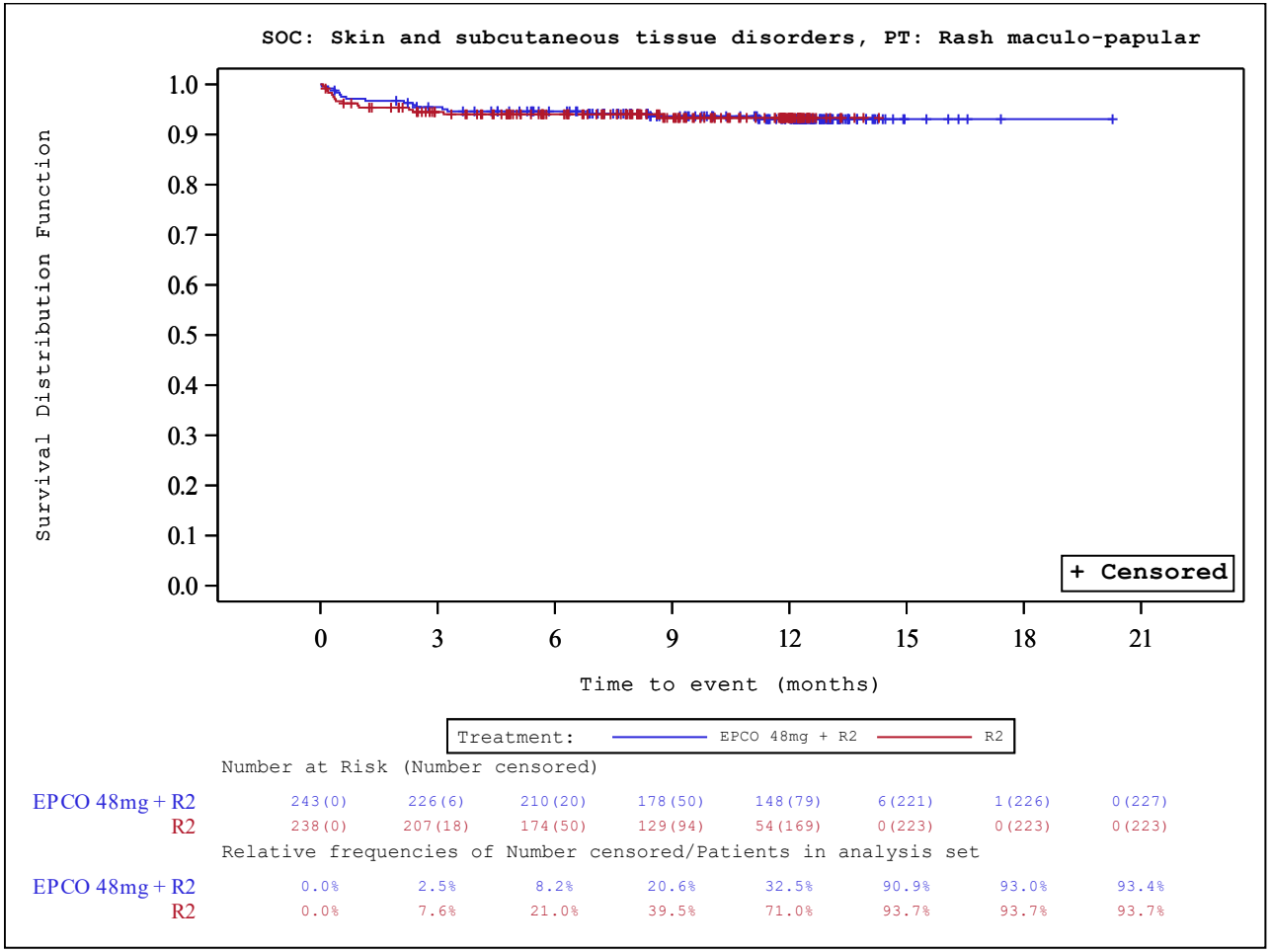
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



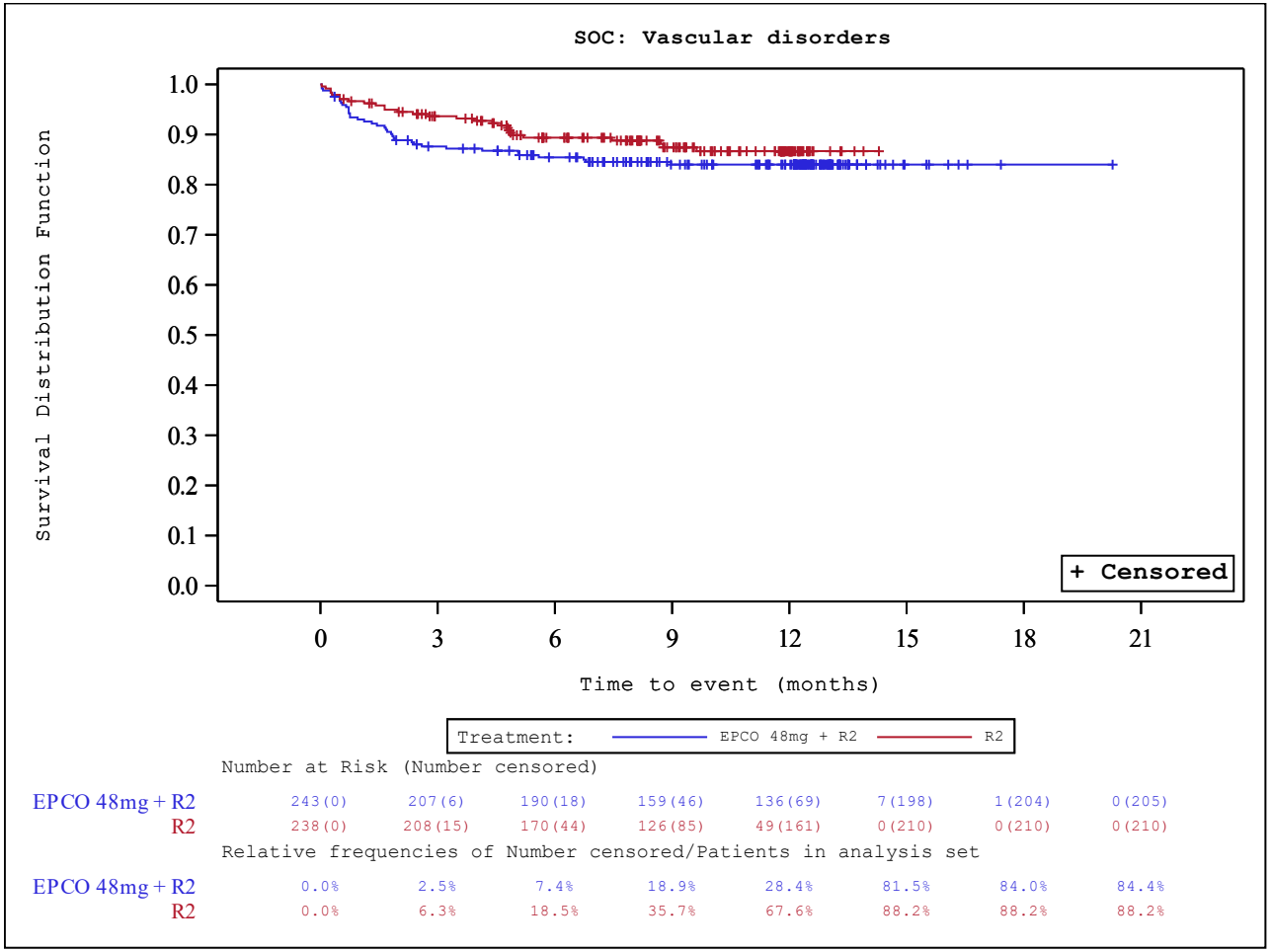
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



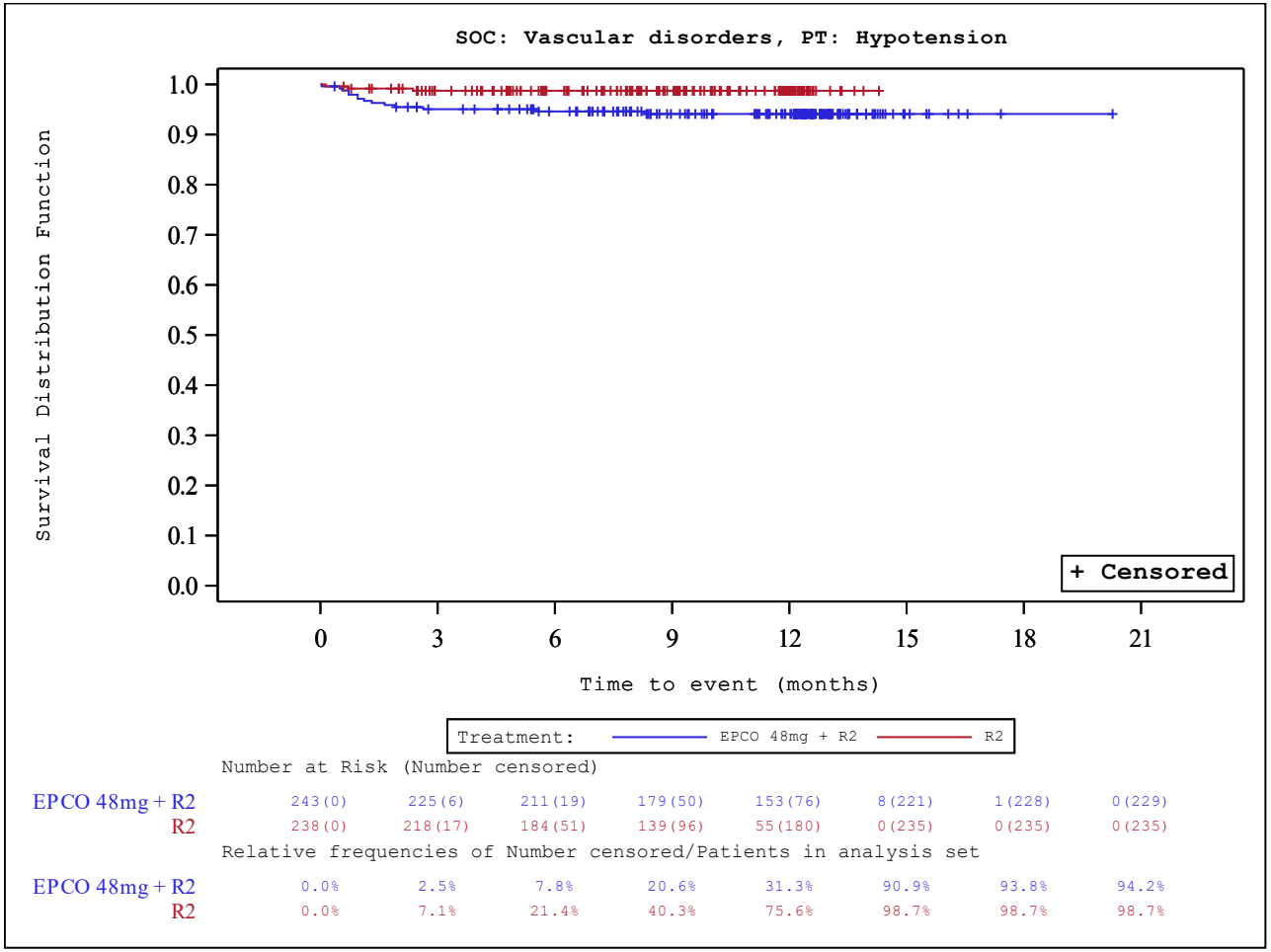
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.1 Kaplan-Meier Plot of Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders	Age (years)							0.1677
	<65	104/ 155 (67.1)	2.60 (1.68, 4.73)	53/ 137 (38.7)	NE (9.49, NE)	2.13 (1.53, 2.96)	<.0001	
	>=65	64/ 88 (72.7)	2.53 (1.64, 3.71)	55/ 101 (54.5)	7.06 (3.19, NE)	1.52 (1.06, 2.19)	0.0202	
	Sex							0.0576
	Male	89/ 139 (64.0)	3.78 (2.56, 6.51)	61/ 135 (45.2)	NE (4.67, NE)	1.50 (1.08, 2.07)	0.0143	
	Female	79/ 104 (76.0)	1.74 (0.89, 2.53)	47/ 103 (45.6)	NE (7.06, NE)	2.36 (1.64, 3.39)	<.0001	
	Disease Status 2L							0.4822
	2L: progression of disease <= 2 years	42/ 63 (66.7)	2.56 (1.64, 6.11)	28/ 61 (45.9)	9.63 (3.75, NE)	1.53 (0.94, 2.46)	0.0796	
	2L: progression of disease > 2 years	64/ 94 (68.1)	4.63 (2.60, 6.51)	38/ 94 (40.4)	NE (7.39, NE)	1.97 (1.32, 2.94)	0.0007	
	Disease Status 3L+							0.4138
	3L+: < 6 months	17/ 23 (73.9)	0.69 (0.49, 1.64)	10/ 22 (45.5)	NE (0.69, NE)	2.17 (0.99, 4.76)	0.0458	
	3L+: >= 6 months	45/ 63 (71.4)	1.84 (1.38, 2.76)	32/ 61 (52.5)	7.98 (3.38, NE)	1.79 (1.13, 2.81)	0.0108	
	Region							0.9229
	US/Western Europe	37/ 58 (63.8)	6.24 (2.33, 11.27)	21/ 57 (36.8)	NE (7.43, NE)	1.84 (1.07, 3.14)	0.0239	
	Rest of world	131/ 185 (70.8)	2.43 (1.64, 2.79)	87/ 181 (48.1)	9.49 (5.59, NE)	1.81 (1.38, 2.38)	<.0001	
	Number of prior anti-lymphoma therapies							0.7467
	2L	106/ 157 (67.5)	3.71 (2.46, 5.85)	66/ 155 (42.6)	NE (7.75, NE)	1.78 (1.31, 2.43)	0.0002	
	3L+	62/ 86 (72.1)	1.63 (1.02, 2.53)	42/ 83 (50.6)	8.25 (3.38, NE)	1.91 (1.29, 2.84)	0.0009	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Anaemia	Age (years)							0.8171
	<65	40/ 155 (25.8)	NE (14.62, NE)	21/ 137 (15.3)	NE (NE , NE)	1.65 (0.97, 2.80)	0.0625	
	>=65	27/ 88 (30.7)	NE (NE , NE)	20/ 101 (19.8)	NE (NE , NE)	1.52 (0.85, 2.72)	0.1504	
	Sex							0.1332
	Male	30/ 139 (21.6)	NE (NE , NE)	23/ 135 (17.0)	NE (NE , NE)	1.20 (0.70, 2.07)	0.5019	
	Female	37/ 104 (35.6)	14.62 (14.62, NE)	18/ 103 (17.5)	NE (NE , NE)	2.09 (1.18, 3.67)	0.0090	
	Disease Status 2L							0.0225
	2L: progression of disease <= 2 years	11/ 63 (17.5)	NE (NE , NE)	14/ 61 (23.0)	NE (NE , NE)	0.69 (0.31, 1.52)	0.3555	
	2L: progression of disease > 2 years	23/ 94 (24.5)	NE (NE , NE)	10/ 94 (10.6)	NE (NE , NE)	2.29 (1.09, 4.81)	0.0244	
	Disease Status 3L+							0.2117
	3L+: < 6 months	10/ 23 (43.5)	NE (0.69, NE)	8/ 22 (36.4)	NE (1.87, NE)	1.30 (0.51, 3.29)	0.5782	
	3L+: >= 6 months	23/ 63 (36.5)	14.62 (NE , NE)	9/ 61 (14.8)	NE (NE , NE)	2.57 (1.18, 5.58)	0.0134	
	Region							0.8138
	US/Western Europe	13/ 58 (22.4)	NE (NE , NE)	7/ 57 (12.3)	NE (NE , NE)	1.71 (0.68, 4.30)	0.2451	
	Rest of world	54/ 185 (29.2)	NE (14.62, NE)	34/ 181 (18.8)	NE (NE , NE)	1.54 (1.00, 2.37)	0.0480	
	Number of prior anti-lymphoma therapies							0.3194
	2L	34/ 157 (21.7)	NE (NE , NE)	24/ 155 (15.5)	NE (NE , NE)	1.33 (0.79, 2.24)	0.2890	
	3L+	33/ 86 (38.4)	14.62 (14.62, NE)	17/ 83 (20.5)	NE (NE , NE)	1.96 (1.09, 3.54)	0.0217	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Age (years)							0.1431
	<65	73/ 155 (47.1)	NE (6.24, NE)	33/ 137 (24.1)	NE (NE , NE)	2.15 (1.43, 3.24)	0.0002	
	>=65	47/ 88 (53.4)	6.47 (2.86, NE)	42/ 101 (41.6)	NE (7.20, NE)	1.38 (0.91, 2.10)	0.1246	
	Sex							0.1619
	Male	65/ 139 (46.8)	12.39 (6.51, NE)	44/ 135 (32.6)	NE (NE , NE)	1.42 (0.97, 2.09)	0.0696	
	Female	55/ 104 (52.9)	6.47 (2.60, NE)	31/ 103 (30.1)	NE (NE , NE)	2.15 (1.38, 3.34)	0.0005	
	Disease Status 2L							0.8453
	2L: progression of disease <= 2 years	31/ 63 (49.2)	9.10 (4.30, NE)	18/ 61 (29.5)	NE (9.07, NE)	1.65 (0.92, 2.96)	0.0864	
	2L: progression of disease > 2 years	41/ 94 (43.6)	NE (6.51, NE)	28/ 94 (29.8)	NE (NE , NE)	1.56 (0.97, 2.53)	0.0655	
	Disease Status 3L+							0.1296
	3L+: < 6 months	12/ 23 (52.2)	3.52 (1.48, NE)	4/ 22 (18.2)	NE (NE , NE)	3.40 (1.09, 10.60)	0.0246	
	3L+: >= 6 months	36/ 63 (57.1)	4.21 (2.53, NE)	25/ 61 (41.0)	NE (6.01, NE)	1.55 (0.93, 2.59)	0.0885	
	Region							0.7365
	US/Western Europe	24/ 58 (41.4)	NE (6.51, NE)	15/ 57 (26.3)	NE (NE , NE)	1.57 (0.82, 2.99)	0.1685	
	Rest of world	96/ 185 (51.9)	7.62 (3.94, NE)	60/ 181 (33.1)	NE (NE , NE)	1.76 (1.27, 2.43)	0.0005	
	Number of prior anti-lymphoma therapies							0.5421
	2L	72/ 157 (45.9)	NE (6.51, NE)	46/ 155 (29.7)	NE (NE , NE)	1.61 (1.11, 2.33)	0.0107	
	3L+	48/ 86 (55.8)	3.75 (2.53, NE)	29/ 83 (34.9)	NE (NE , NE)	1.88 (1.18, 2.98)	0.0064	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions	Age (years)							0.4577
	<65	99/ 155 (63.9)	2.07 (1.31, 3.32)	56/ 137 (40.9)	NE (8.28, NE)	1.69 (1.22, 2.35)	0.0014	
	>=65	65/ 88 (73.9)	1.31 (1.02, 1.97)	45/ 101 (44.6)	NE (3.75, NE)	2.08 (1.42, 3.06)	0.0001	
	Sex							0.6253
	Male	99/ 139 (71.2)	1.35 (1.15, 2.10)	58/ 135 (43.0)	NE (5.62, NE)	1.90 (1.37, 2.63)	<.0001	
	Female	65/ 104 (62.5)	2.04 (1.41, 4.63)	43/ 103 (41.7)	NE (7.46, NE)	1.68 (1.14, 2.48)	0.0077	
	Disease Status 2L							0.2085
	2L: progression of disease <= 2 years	35/ 63 (55.6)	2.37 (1.35, NE)	26/ 61 (42.6)	NE (4.21, NE)	1.23 (0.74, 2.05)	0.4252	
	2L: progression of disease > 2 years	68/ 94 (72.3)	1.64 (0.99, 2.56)	43/ 94 (45.7)	NE (2.83, NE)	1.88 (1.28, 2.76)	0.0009	
	Disease Status 3L+							0.4622
	3L+: < 6 months	14/ 23 (60.9)	2.60 (1.18, NE)	8/ 22 (36.4)	NE (0.59, NE)	1.78 (0.74, 4.27)	0.1859	
	3L+: >= 6 months	47/ 63 (74.6)	1.25 (0.95, 1.58)	24/ 61 (39.3)	NE (7.46, NE)	2.53 (1.53, 4.16)	0.0001	
	Region							0.8845
	US/Western Europe	47/ 58 (81.0)	1.18 (0.82, 2.04)	29/ 57 (50.9)	7.46 (0.82, NE)	1.75 (1.10, 2.79)	0.0159	
	Rest of world	117/ 185 (63.2)	1.97 (1.35, 2.73)	72/ 181 (39.8)	NE (9.36, NE)	1.83 (1.37, 2.46)	<.0001	
	Number of prior anti-lymphoma therapies							0.1597
	2L	103/ 157 (65.6)	2.10 (1.22, 3.02)	69/ 155 (44.5)	NE (4.63, NE)	1.59 (1.17, 2.16)	0.0025	
	3L+	61/ 86 (70.9)	1.43 (1.05, 1.91)	32/ 83 (38.6)	NE (8.54, NE)	2.31 (1.50, 3.56)	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Injection site erythema	Age (years)							
	<65	8/ 155 (5.2)		0/ 137 (0.0)				
	>=65	5/ 88 (5.7)		0/ 101 (0.0)				
	Sex							
	Male	8/ 139 (5.8)		0/ 135 (0.0)				
	Female	5/ 104 (4.8)		0/ 103 (0.0)				
	Disease Status 2L							
	2L: progression of disease <= 2 years	2/ 63 (3.2)		0/ 61 (0.0)				
	2L: progression of disease > 2 years	6/ 94 (6.4)		0/ 94 (0.0)				
	Disease Status 3L+							
	3L+: < 6 months	1/ 23 (4.3)		0/ 22 (0.0)				
	3L+: >= 6 months	4/ 63 (6.3)		0/ 61 (0.0)				
	Region							
	US/Western Europe	5/ 58 (8.6)		0/ 57 (0.0)				
	Rest of world	8/ 185 (4.3)		0/ 181 (0.0)				
	Number of prior anti-lymphoma therapies							
	2L	8/ 157 (5.1)		0/ 155 (0.0)				
	3L+	5/ 86 (5.8)		0/ 83 (0.0)				

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Injection site reaction	Age (years)							0.9999
	<65	33/ 155 (21.3)	NE (NE , NE)	0/ 137 (0.0)	NE (NE , NE)	NE		
	>=65	20/ 88 (22.7)	NE (NE , NE)	0/ 101 (0.0)	NE (NE , NE)	NE		
	Sex							1.0000
	Male	30/ 139 (21.6)	NE (NE , NE)	0/ 135 (0.0)	NE (NE , NE)	NE		
	Female	23/ 104 (22.1)	NE (NE , NE)	0/ 103 (0.0)	NE (NE , NE)	NE		
	Disease Status 2L							0.9999
	2L: progression of disease <= 2 years	13/ 63 (20.6)	NE (NE , NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
	2L: progression of disease > 2 years	21/ 94 (22.3)	NE (NE , NE)	0/ 94 (0.0)	NE (NE , NE)	NE		
	Disease Status 3L+							0.9969
	3L+: < 6 months	0/ 23 (0.0)	NE (NE , NE)	0/ 22 (0.0)	NE (NE , NE)	NE		
	3L+: >= 6 months	19/ 63 (30.2)	NE (NE , NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
	Region							0.9999
	US/Western Europe	15/ 58 (25.9)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
	Rest of world	38/ 185 (20.5)	NE (NE , NE)	0/ 181 (0.0)	NE (NE , NE)	NE		
	Number of prior anti-lymphoma therapies							1.0000
	2L	34/ 157 (21.7)	NE (NE , NE)	0/ 155 (0.0)	NE (NE , NE)	NE		
	3L+	19/ 86 (22.1)	NE (NE , NE)	0/ 83 (0.0)	NE (NE , NE)	NE		

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: General disorders and administration site conditions, PT: Pyrexia	Age (years)							0.1930
	<65	41/ 155 (26.5)	NE (NE , NE)	17/ 137 (12.4)	NE (NE , NE)	2.13 (1.21, 3.75)	0.0071	
	>=65	17/ 88 (19.3)	NE (NE , NE)	16/ 101 (15.8)	NE (NE , NE)	1.20 (0.60, 2.37)	0.6078	
	Sex							0.6353
	Male	35/ 139 (25.2)	NE (NE , NE)	21/ 135 (15.6)	NE (NE , NE)	1.57 (0.91, 2.69)	0.0998	
	Female	23/ 104 (22.1)	NE (NE , NE)	12/ 103 (11.7)	NE (NE , NE)	1.93 (0.96, 3.88)	0.0595	
	Disease Status 2L							0.2502
	2L: progression of disease <= 2 years	16/ 63 (25.4)	NE (NE , NE)	12/ 61 (19.7)	NE (NE , NE)	1.20 (0.57, 2.55)	0.6306	
	2L: progression of disease > 2 years	24/ 94 (25.5)	NE (NE , NE)	11/ 94 (11.7)	NE (NE , NE)	2.22 (1.09, 4.54)	0.0240	
	Disease Status 3L+							0.2014
	3L+: < 6 months	6/ 23 (26.1)	NE (2.92, NE)	1/ 22 (4.5)	NE (NE , NE)	6.20 (0.74, 51.53)	0.0536	
	3L+: >= 6 months	12/ 63 (19.0)	NE (NE , NE)	9/ 61 (14.8)	NE (NE , NE)	1.28 (0.54, 3.04)	0.5727	
	Region							0.2193
	US/Western Europe	9/ 58 (15.5)	NE (NE , NE)	8/ 57 (14.0)	NE (NE , NE)	1.03 (0.40, 2.66)	0.9566	
	Rest of world	49/ 185 (26.5)	NE (NE , NE)	25/ 181 (13.8)	NE (NE , NE)	1.95 (1.21, 3.16)	0.0055	
	Number of prior anti-lymphoma therapies							0.9135
	2L	40/ 157 (25.5)	NE (NE , NE)	23/ 155 (14.8)	NE (NE , NE)	1.68 (1.01, 2.81)	0.0436	
	3L+	18/ 86 (20.9)	NE (NE , NE)	10/ 83 (12.0)	NE (NE , NE)	1.74 (0.81, 3.78)	0.1526	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Hepatobiliary disorders	Age (years)							
	<65	8/ 155 (5.2)		1/ 137 (0.7)				
	>=65	4/ 88 (4.5)		1/ 101 (1.0)				
	Sex							
	Male	5/ 139 (3.6)		1/ 135 (0.7)				
	Female	7/ 104 (6.7)		1/ 103 (1.0)				
	Disease Status 2L							
	2L: progression of disease <= 2 years	4/ 63 (6.3)		0/ 61 (0.0)				
	2L: progression of disease > 2 years	4/ 94 (4.3)		2/ 94 (2.1)				
	Disease Status 3L+							
	3L+: < 6 months	0/ 23 (0.0)		0/ 22 (0.0)				
	3L+: >= 6 months	4/ 63 (6.3)		0/ 61 (0.0)				
	Region							0.9929
	US/Western Europe	3/ 58 (5.2)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
	Rest of world	9/ 185 (4.9)	NE (NE , NE)	2/ 181 (1.1)	NE (NE , NE)	4.00 (0.86, 18.62)	0.0561	
	Number of prior anti-lymphoma therapies							0.9913
	2L	8/ 157 (5.1)	NE (NE , NE)	2/ 155 (1.3)	NE (NE , NE)	3.43 (0.72, 16.25)	0.0992	
	3L+	4/ 86 (4.7)	NE (NE , NE)	0/ 83 (0.0)	NE (NE , NE)	NE		

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders	Age (years)							0.2831
	<65	78/ 155 (50.3)	10.45 (1.87, NE)	9/ 137 (6.6)	NE (NE , NE)	9.67 (4.84, 19.31)	<.0001	
	>=65	37/ 88 (42.0)	NE (6.74, NE)	9/ 101 (8.9)	NE (NE , NE)	5.50 (2.65, 11.40)	<.0001	
	Sex							0.7217
	Male	61/ 139 (43.9)	NE (7.00, NE)	8/ 135 (5.9)	NE (NE , NE)	8.59 (4.11, 17.97)	<.0001	
	Female	54/ 104 (51.9)	9.20 (0.95, NE)	10/ 103 (9.7)	NE (NE , NE)	7.04 (3.58, 13.84)	<.0001	
	Disease Status 2L							0.9778
	2L: progression of disease <= 2 years	35/ 63 (55.6)	7.16 (0.89, NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
	2L: progression of disease > 2 years	40/ 94 (42.6)	NE (6.34, NE)	10/ 94 (10.6)	NE (NE , NE)	4.80 (2.40, 9.60)	<.0001	
	Disease Status 3L+							0.6758
	3L+: < 6 months	11/ 23 (47.8)	NE (0.59, NE)	3/ 22 (13.6)	NE (NE , NE)	4.51 (1.25, 16.24)	0.0113	
	3L+: >= 6 months	29/ 63 (46.0)	NE (5.36, NE)	5/ 61 (8.2)	NE (NE , NE)	6.84 (2.65, 17.68)	<.0001	
	Region							0.0044
	US/Western Europe	24/ 58 (41.4)	NE (5.36, NE)	9/ 57 (15.8)	NE (NE , NE)	2.80 (1.30, 6.02)	0.0056	
	Rest of world	91/ 185 (49.2)	11.60 (4.93, NE)	9/ 181 (5.0)	NE (NE , NE)	12.83 (6.46, 25.47)	<.0001	
	Number of prior anti-lymphoma therapies							0.3740
	2L	75/ 157 (47.8)	13.04 (2.99, NE)	10/ 155 (6.5)	NE (NE , NE)	9.02 (4.66, 17.47)	<.0001	
	3L+	40/ 86 (46.5)	NE (4.93, NE)	8/ 83 (9.6)	NE (NE , NE)	6.00 (2.81, 12.83)	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders, PT: Cytokine release syndrome	Age (years)							0.9782
	<65	58/ 155 (37.4)	NE (NE , NE)	0/ 137 (0.0)	NE (NE , NE)	NE		
	>=65	27/ 88 (30.7)	NE (NE , NE)	1/ 101 (1.0)	NE (NE , NE)	36.29 (4.93, 267.19)	<.0001	
	Sex							0.9818
	Male	43/ 139 (30.9)	NE (NE , NE)	1/ 135 (0.7)	NE (NE , NE)	48.87 (6.73, 354.74)	<.0001	
	Female	42/ 104 (40.4)	NE (1.68, NE)	0/ 103 (0.0)	NE (NE , NE)	NE		
	Disease Status 2L							0.9849
	2L: progression of disease <= 2 years	26/ 63 (41.3)	NE (0.89, NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
	2L: progression of disease > 2 years	34/ 94 (36.2)	NE (NE , NE)	1/ 94 (1.1)	NE (NE , NE)	41.11 (5.63, 300.43)	<.0001	
	Disease Status 3L+							0.9998
	3L+: < 6 months	10/ 23 (43.5)	NE (0.89, NE)	0/ 22 (0.0)	NE (NE , NE)	NE		
	3L+: >= 6 months	15/ 63 (23.8)	NE (NE , NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
	Region							0.9830
	US/Western Europe	20/ 58 (34.5)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	22.72 (3.05, 169.41)	<.0001	
	Rest of world	65/ 185 (35.1)	NE (NE , NE)	0/ 181 (0.0)	NE (NE , NE)	NE		
	Number of prior anti-lymphoma therapies							0.9845
	2L	60/ 157 (38.2)	NE (NE , NE)	1/ 155 (0.6)	NE (NE , NE)	72.50 (10.04, 523.25)	<.0001	
	3L+	25/ 86 (29.1)	NE (NE , NE)	0/ 83 (0.0)	NE (NE , NE)	NE		

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders, PT: Hypogammaglobulinaemia	Age (years)							0.3642
	<65	29/ 155 (18.7)	NE (NE , NE)	7/ 137 (5.1)	NE (NE , NE)	3.50 (1.53, 7.99)	0.0015	
	>=65	18/ 88 (20.5)	NE (NE , NE)	3/ 101 (3.0)	NE (NE , NE)	6.99 (2.06, 23.73)	0.0003	
	Sex							0.0886
	Male	29/ 139 (20.9)	NE (NE , NE)	3/ 135 (2.2)	NE (NE , NE)	9.14 (2.78, 30.01)	<.0001	
	Female	18/ 104 (17.3)	NE (NE , NE)	7/ 103 (6.8)	NE (NE , NE)	2.50 (1.04, 5.99)	0.0330	
	Disease Status 2L							0.9867
	2L: progression of disease <= 2 years	11/ 63 (17.5)	NE (NE , NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
	2L: progression of disease > 2 years	14/ 94 (14.9)	NE (NE , NE)	5/ 94 (5.3)	NE (NE , NE)	2.75 (0.99, 7.62)	0.0431	
	Disease Status 3L+							0.8978
	3L+: < 6 months	4/ 23 (17.4)	NE (NE , NE)	1/ 22 (4.5)	NE (NE , NE)	3.59 (0.40, 32.26)	0.2233	
	3L+: >= 6 months	18/ 63 (28.6)	NE (NE , NE)	4/ 61 (6.6)	NE (NE , NE)	4.62 (1.56, 13.65)	0.0023	
	Region							0.5278
	US/Western Europe	10/ 58 (17.2)	NE (NE , NE)	3/ 57 (5.3)	NE (NE , NE)	3.15 (0.87, 11.46)	0.0646	
	Rest of world	37/ 185 (20.0)	NE (NE , NE)	7/ 181 (3.9)	NE (NE , NE)	5.10 (2.27, 11.44)	<.0001	
	Number of prior anti-lymphoma therapies							0.9443
	2L	25/ 157 (15.9)	NE (NE , NE)	5/ 155 (3.2)	NE (NE , NE)	4.63 (1.77, 12.10)	0.0006	
	3L+	22/ 86 (25.6)	NE (NE , NE)	5/ 83 (6.0)	NE (NE , NE)	4.46 (1.69, 11.77)	0.0009	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	Age (years)							0.6198
	<65	119/ 155 (76.8)	2.96 (2.10, 4.24)	71/ 137 (51.8)	8.67 (5.65, 11.10)	1.86 (1.39, 2.50)	<.0001	
	>=65	69/ 88 (78.4)	2.76 (1.81, 4.37)	54/ 101 (53.5)	6.90 (4.60, 10.18)	1.66 (1.16, 2.37)	0.0049	
	Sex							0.2914
	Male	109/ 139 (78.4)	3.02 (2.20, 3.91)	65/ 135 (48.1)	8.71 (5.65, NE)	1.97 (1.45, 2.69)	<.0001	
	Female	79/ 104 (76.0)	2.76 (1.81, 4.60)	60/ 103 (58.3)	7.56 (3.84, 9.92)	1.53 (1.09, 2.14)	0.0129	
	Disease Status 2L							0.8668
	2L: progression of disease <= 2 years	48/ 63 (76.2)	3.15 (1.87, 5.55)	29/ 61 (47.5)	9.03 (4.60, NE)	1.77 (1.12, 2.82)	0.0137	
	2L: progression of disease > 2 years	71/ 94 (75.5)	3.12 (1.71, 4.63)	50/ 94 (53.2)	7.39 (5.65, NE)	1.71 (1.19, 2.46)	0.0032	
	Disease Status 3L+							0.1227
	3L+: < 6 months	18/ 23 (78.3)	6.01 (1.38, 7.43)	15/ 22 (68.2)	5.09 (2.33, 8.97)	0.99 (0.49, 1.98)	0.9680	
	3L+: >= 6 months	51/ 63 (81.0)	2.56 (1.35, 3.55)	31/ 61 (50.8)	9.46 (3.52, NE)	2.10 (1.34, 3.29)	0.0009	
	Region							0.9319
	US/Western Europe	47/ 58 (81.0)	2.37 (1.45, 4.01)	31/ 57 (54.4)	5.91 (3.52, NE)	1.79 (1.14, 2.83)	0.0103	
	Rest of world	141/ 185 (76.2)	3.02 (2.40, 4.50)	94/ 181 (51.9)	8.31 (5.65, 10.15)	1.76 (1.36, 2.29)	<.0001	
	Number of prior anti-lymphoma therapies							0.9162
	2L	119/ 157 (75.8)	3.12 (2.27, 4.24)	79/ 155 (51.0)	7.98 (5.91, 11.10)	1.75 (1.31, 2.32)	0.0001	
	3L+	69/ 86 (80.2)	2.60 (1.68, 4.60)	46/ 83 (55.4)	5.75 (4.30, 10.18)	1.81 (1.24, 2.63)	0.0016	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	Age (years)							0.5476
	<65	3/ 155 (1.9)	NE (NE , NE)	1/ 137 (0.7)	NE (NE , NE)	2.24 (0.23, 21.61)	0.4729	
	>=65	10/ 88 (11.4)	NE (NE , NE)	2/ 101 (2.0)	NE (NE , NE)	5.36 (1.17, 24.51)	0.0151	
	Sex							
	Male	8/ 139 (5.8)		1/ 135 (0.7)				
	Female	5/ 104 (4.8)		2/ 103 (1.9)				
	Disease Status 2L							
	2L: progression of disease <= 2 years	3/ 63 (4.8)		0/ 61 (0.0)				
	2L: progression of disease > 2 years	6/ 94 (6.4)		2/ 94 (2.1)				
	Disease Status 3L+							
	3L+: < 6 months	0/ 23 (0.0)		1/ 22 (4.5)				
	3L+: >= 6 months	4/ 63 (6.3)		0/ 61 (0.0)				
	Region							0.6984
	US/Western Europe	10/ 58 (17.2)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	4.45 (0.98, 20.33)	0.0345	
	Rest of world	3/ 185 (1.6)	NE (NE , NE)	1/ 181 (0.6)	NE (NE , NE)	2.51 (0.26, 24.23)	0.4114	
	Number of prior anti-lymphoma therapies							0.9605
	2L	9/ 157 (5.7)	NE (NE , NE)	2/ 155 (1.3)	NE (NE , NE)	4.03 (0.87, 18.67)	0.0539	
	3L+	4/ 86 (4.7)	NE (NE , NE)	1/ 83 (1.2)	NE (NE , NE)	3.46 (0.39, 30.96)	0.2376	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: COVID-19 pneumonia	Age (years)							
	<65	5/ 155 (3.2)		0/ 137 (0.0)				
	>=65	6/ 88 (6.8)		1/ 101 (1.0)				
	Sex							
	Male	7/ 139 (5.0)		0/ 135 (0.0)				
	Female	4/ 104 (3.8)		1/ 103 (1.0)				
	Disease Status 2L							
	2L: progression of disease <= 2 years	5/ 63 (7.9)		0/ 61 (0.0)				
	2L: progression of disease > 2 years	4/ 94 (4.3)		1/ 94 (1.1)				
	Disease Status 3L+							
	3L+: < 6 months	2/ 23 (8.7)		0/ 22 (0.0)				
	3L+: >= 6 months	0/ 63 (0.0)		0/ 61 (0.0)				
	Region							0.9942
	US/Western Europe	2/ 58 (3.4)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
	Rest of world	9/ 185 (4.9)	NE (NE , NE)	1/ 181 (0.6)	NE (NE , NE)	6.98 (0.87, 55.72)	0.0333	
	Number of prior anti-lymphoma therapies							0.9934
	2L	9/ 157 (5.7)	NE (14.23, NE)	1/ 155 (0.6)	NE (NE , NE)	6.97 (0.87, 55.84)	0.0332	
	3L+	2/ 86 (2.3)	NE (NE , NE)	0/ 83 (0.0)	NE (NE , NE)	NE		

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Pneumonia	Age (years)							0.6712
	<65	31/ 155 (20.0)	NE (NE , NE)	13/ 137 (9.5)	NE (NE , NE)	1.88 (0.98, 3.60)	0.0520	
	>=65	16/ 88 (18.2)	NE (NE , NE)	7/ 101 (6.9)	NE (NE , NE)	2.40 (0.98, 5.85)	0.0473	
	Sex							0.2767
	Male	35/ 139 (25.2)	NE (NE , NE)	12/ 135 (8.9)	NE (NE , NE)	2.49 (1.29, 4.81)	0.0048	
	Female	12/ 104 (11.5)	NE (NE , NE)	8/ 103 (7.8)	NE (NE , NE)	1.38 (0.56, 3.38)	0.4783	
	Disease Status 2L							0.1951
	2L: progression of disease <= 2 years	6/ 63 (9.5)	NE (NE , NE)	6/ 61 (9.8)	NE (NE , NE)	0.75 (0.24, 2.35)	0.6204	
	2L: progression of disease > 2 years	14/ 94 (14.9)	NE (NE , NE)	7/ 94 (7.4)	NE (NE , NE)	1.87 (0.75, 4.63)	0.1702	
	Disease Status 3L+							0.8099
	3L+: < 6 months	9/ 23 (39.1)	NE (7.79, NE)	2/ 22 (9.1)	NE (NE , NE)	4.32 (0.93, 20.03)	0.0414	
	3L+: >= 6 months	18/ 63 (28.6)	NE (NE , NE)	5/ 61 (8.2)	NE (NE , NE)	3.42 (1.27, 9.22)	0.0097	
	Region							0.6904
	US/Western Europe	8/ 58 (13.8)	NE (NE , NE)	4/ 57 (7.0)	NE (NE , NE)	1.64 (0.49, 5.49)	0.4196	
	Rest of world	39/ 185 (21.1)	NE (NE , NE)	16/ 181 (8.8)	NE (NE , NE)	2.21 (1.23, 3.96)	0.0062	
	Number of prior anti-lymphoma therapies							0.0573
	2L	20/ 157 (12.7)	NE (NE , NE)	13/ 155 (8.4)	NE (NE , NE)	1.31 (0.65, 2.63)	0.4526	
	3L+	27/ 86 (31.4)	NE (NE , NE)	7/ 83 (8.4)	NE (NE , NE)	3.68 (1.60, 8.46)	0.0010	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Rhinovirus infection	Age (years)							0.5917
	<65	9/ 155 (5.8)	NE (NE , NE)	1/ 137 (0.7)	NE (NE , NE)	7.66 (0.97, 60.47)	0.0224	
	>=65	3/ 88 (3.4)	NE (NE , NE)	1/ 101 (1.0)	NE (NE , NE)	3.00 (0.31, 29.10)	0.3187	
	Sex							
	Male	6/ 139 (4.3)		1/ 135 (0.7)				
	Female	6/ 104 (5.8)		1/ 103 (1.0)				
	Disease Status 2L							
	2L: progression of disease <= 2 years	3/ 63 (4.8)		0/ 61 (0.0)				
	2L: progression of disease > 2 years	4/ 94 (4.3)		2/ 94 (2.1)				
	Disease Status 3L+							
	3L+: < 6 months	1/ 23 (4.3)		0/ 22 (0.0)				
	3L+: >= 6 months	4/ 63 (6.3)		0/ 61 (0.0)				
	Region							0.1641
	US/Western Europe	1/ 58 (1.7)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	0.88 (0.05, 14.07)	0.9258	
	Rest of world	11/ 185 (5.9)	NE (NE , NE)	1/ 181 (0.6)	NE (NE , NE)	10.26 (1.32, 79.53)	0.0057	
	Number of prior anti-lymphoma therapies							
	2L	7/ 157 (4.5)		2/ 155 (1.3)				
	3L+	5/ 86 (5.8)		0/ 83 (0.0)				

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Investigations	Age (years)							0.7708
	<65	99/ 155 (63.9)	2.27 (1.38, 7.29)	54/ 137 (39.4)	NE (10.18, NE)	1.78 (1.28, 2.48)	0.0005	
	>=65	52/ 88 (59.1)	5.68 (1.87, 10.84)	40/ 101 (39.6)	NE (9.40, NE)	1.69 (1.12, 2.55)	0.0114	
	Sex							0.6493
	Male	86/ 139 (61.9)	4.67 (1.87, 7.59)	53/ 135 (39.3)	NE (7.39, NE)	1.69 (1.20, 2.37)	0.0023	
	Female	65/ 104 (62.5)	2.79 (0.95, 8.28)	41/ 103 (39.8)	NE (9.49, NE)	1.87 (1.27, 2.77)	0.0013	
	Disease Status 2L							0.3624
	2L: progression of disease <= 2 years	38/ 63 (60.3)	2.33 (0.92, NE)	26/ 61 (42.6)	NE (4.63, NE)	1.48 (0.90, 2.43)	0.1195	
	2L: progression of disease > 2 years	55/ 94 (58.5)	4.63 (1.68, 10.84)	31/ 94 (33.0)	NE (NE , NE)	2.02 (1.30, 3.14)	0.0013	
	Disease Status 3L+							0.8881
	3L+: < 6 months	17/ 23 (73.9)	0.92 (0.49, 7.20)	11/ 22 (50.0)	5.55 (1.41, NE)	1.85 (0.87, 3.97)	0.1048	
	3L+: >= 6 months	41/ 63 (65.1)	5.68 (1.61, 8.48)	26/ 61 (42.6)	NE (6.67, NE)	1.77 (1.08, 2.89)	0.0209	
	Region							0.0519
	US/Western Europe	30/ 58 (51.7)	8.48 (2.79, NE)	26/ 57 (45.6)	NE (3.78, NE)	1.12 (0.66, 1.90)	0.6603	
	Rest of world	121/ 185 (65.4)	2.10 (1.38, 6.70)	68/ 181 (37.6)	NE (NE , NE)	2.02 (1.50, 2.72)	<.0001	
	Number of prior anti-lymphoma therapies							0.9796
	2L	93/ 157 (59.2)	3.81 (1.68, 9.20)	57/ 155 (36.8)	NE (NE , NE)	1.77 (1.27, 2.46)	0.0005	
	3L+	58/ 86 (67.4)	3.78 (1.18, 7.92)	37/ 83 (44.6)	NE (5.36, NE)	1.78 (1.18, 2.69)	0.0052	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Alanine aminotransferase increased	Age (years)							0.8333
	<65	37/ 155 (23.9)	NE (NE , NE)	18/ 137 (13.1)	NE (NE , NE)	1.74 (0.99, 3.05)	0.0510	
	>=65	9/ 88 (10.2)	NE (NE , NE)	5/ 101 (5.0)	NE (NE , NE)	1.92 (0.64, 5.76)	0.2359	
	Sex							0.3561
	Male	22/ 139 (15.8)	NE (NE , NE)	13/ 135 (9.6)	NE (NE , NE)	1.46 (0.73, 2.90)	0.2832	
	Female	24/ 104 (23.1)	NE (NE , NE)	10/ 103 (9.7)	NE (NE , NE)	2.41 (1.15, 5.04)	0.0155	
	Disease Status 2L							0.5169
	2L: progression of disease <= 2 years	13/ 63 (20.6)	NE (NE , NE)	6/ 61 (9.8)	NE (NE , NE)	1.91 (0.72, 5.05)	0.1821	
	2L: progression of disease > 2 years	15/ 94 (16.0)	NE (NE , NE)	11/ 94 (11.7)	NE (NE , NE)	1.31 (0.60, 2.85)	0.4934	
	Disease Status 3L+							0.9589
	3L+: < 6 months	9/ 23 (39.1)	NE (7.20, NE)	3/ 22 (13.6)	NE (NE , NE)	2.52 (0.67, 9.46)	0.1556	
	3L+: >= 6 months	9/ 63 (14.3)	NE (NE , NE)	3/ 61 (4.9)	NE (NE , NE)	2.90 (0.79, 10.72)	0.0937	
	Region							0.3820
	US/Western Europe	5/ 58 (8.6)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	4.60 (0.54, 39.39)	0.1251	
	Rest of world	41/ 185 (22.2)	NE (NE , NE)	22/ 181 (12.2)	NE (NE , NE)	1.73 (1.03, 2.91)	0.0356	
	Number of prior anti-lymphoma therapies							0.2764
	2L	28/ 157 (17.8)	NE (NE , NE)	17/ 155 (11.0)	NE (NE , NE)	1.54 (0.84, 2.82)	0.1562	
	3L+	18/ 86 (20.9)	NE (NE , NE)	6/ 83 (7.2)	NE (NE , NE)	2.78 (1.10, 7.02)	0.0236	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Blood creatinine increased	Age (years)							0.7210
	<65	10/ 155 (6.5)	NE (NE , NE)	4/ 137 (2.9)	NE (NE , NE)	2.19 (0.69, 6.99)	0.1725	
	>=65	10/ 88 (11.4)	NE (NE , NE)	4/ 101 (4.0)	NE (NE , NE)	2.79 (0.87, 8.91)	0.0711	
	Sex							0.9368
	Male	10/ 139 (7.2)	NE (NE , NE)	4/ 135 (3.0)	NE (NE , NE)	2.33 (0.73, 7.44)	0.1406	
	Female	10/ 104 (9.6)	NE (NE , NE)	4/ 103 (3.9)	NE (NE , NE)	2.51 (0.79, 8.01)	0.1064	
	Disease Status 2L							0.3518
	2L: progression of disease <= 2 years	1/ 63 (1.6)	NE (NE , NE)	1/ 61 (1.6)	NE (NE , NE)	0.94 (0.06, 15.10)	0.9677	
	2L: progression of disease > 2 years	8/ 94 (8.5)	NE (NE , NE)	2/ 94 (2.1)	NE (NE , NE)	3.98 (0.85, 18.76)	0.0587	
	Disease Status 3L+							0.9243
	3L+: < 6 months	2/ 23 (8.7)	NE (NE , NE)	1/ 22 (4.5)	NE (NE , NE)	1.97 (0.18, 21.78)	0.5714	
	3L+: >= 6 months	9/ 63 (14.3)	NE (NE , NE)	4/ 61 (6.6)	NE (NE , NE)	2.23 (0.69, 7.26)	0.1687	
	Region							0.2987
	US/Western Europe	2/ 58 (3.4)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	0.88 (0.12, 6.29)	0.9012	
	Rest of world	18/ 185 (9.7)	NE (NE , NE)	6/ 181 (3.3)	NE (NE , NE)	2.95 (1.17, 7.44)	0.0158	
	Number of prior anti-lymphoma therapies							0.7555
	2L	9/ 157 (5.7)	NE (NE , NE)	3/ 155 (1.9)	NE (NE , NE)	2.86 (0.77, 10.57)	0.0998	
	3L+	11/ 86 (12.8)	NE (NE , NE)	5/ 83 (6.0)	NE (NE , NE)	2.19 (0.76, 6.31)	0.1350	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	EPCO 48mg + R2 vs. R2 p-Value	Interaction p-Value
SOC: Investigations, PT: Gamma-glutamyltransferase increased	Age (years)							
	<65	9/ 155 (5.8)		0/ 137 (0.0)				
	>=65	3/ 88 (3.4)		0/ 101 (0.0)				
	Sex							0.9995
	Male	2/ 139 (1.4)	NE (NE , NE)	0/ 135 (0.0)	NE (NE , NE)	NE		
	Female	10/ 104 (9.6)	NE (NE , NE)	0/ 103 (0.0)	NE (NE , NE)	NE		
	Disease Status 2L							
	2L: progression of disease <= 2 years	5/ 63 (7.9)		0/ 61 (0.0)				
	2L: progression of disease > 2 years	3/ 94 (3.2)		0/ 94 (0.0)				
	Disease Status 3L+							
	3L+: < 6 months	0/ 23 (0.0)		0/ 22 (0.0)				
	3L+: >= 6 months	4/ 63 (6.3)		0/ 61 (0.0)				
	Region							0.9999
	US/Western Europe	2/ 58 (3.4)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
	Rest of world	10/ 185 (5.4)	NE (NE , NE)	0/ 181 (0.0)	NE (NE , NE)	NE		
	Number of prior anti-lymphoma therapies							
	2L	8/ 157 (5.1)		0/ 155 (0.0)				
	3L+	4/ 86 (4.7)		0/ 83 (0.0)				

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Platelet count decreased	Age (years)							0.6683
	<65	24/ 155 (15.5)	NE (NE , NE)	9/ 137 (6.6)	NE (NE , NE)	2.35 (1.09, 5.06)	0.0239	
	>=65	11/ 88 (12.5)	NE (NE , NE)	4/ 101 (4.0)	NE (NE , NE)	3.31 (1.06, 10.41)	0.0294	
	Sex							0.3334
	Male	22/ 139 (15.8)	NE (NE , NE)	10/ 135 (7.4)	NE (NE , NE)	2.17 (1.03, 4.58)	0.0374	
	Female	13/ 104 (12.5)	NE (NE , NE)	3/ 103 (2.9)	NE (NE , NE)	4.35 (1.24, 15.28)	0.0119	
	Disease Status 2L							0.9733
	2L: progression of disease <= 2 years	10/ 63 (15.9)	NE (NE , NE)	2/ 61 (3.3)	NE (NE , NE)	4.78 (1.05, 21.84)	0.0255	
	2L: progression of disease > 2 years	14/ 94 (14.9)	NE (NE , NE)	3/ 94 (3.2)	NE (NE , NE)	4.77 (1.37, 16.60)	0.0066	
	Disease Status 3L+							0.1296
	3L+: < 6 months	5/ 23 (21.7)	NE (NE , NE)	1/ 22 (4.5)	NE (NE , NE)	5.33 (0.62, 45.61)	0.0872	
	3L+: >= 6 months	6/ 63 (9.5)	NE (NE , NE)	7/ 61 (11.5)	NE (NE , NE)	0.83 (0.28, 2.46)	0.7290	
	Region							0.9124
	US/Western Europe	6/ 58 (10.3)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	2.90 (0.59, 14.39)	0.1707	
	Rest of world	29/ 185 (15.7)	NE (NE , NE)	11/ 181 (6.1)	NE (NE , NE)	2.63 (1.31, 5.26)	0.0045	
	Number of prior anti-lymphoma therapies							0.0658
	2L	24/ 157 (15.3)	NE (NE , NE)	5/ 155 (3.2)	NE (NE , NE)	4.74 (1.81, 12.41)	0.0005	
	3L+	11/ 86 (12.8)	NE (NE , NE)	8/ 83 (9.6)	NE (NE , NE)	1.37 (0.55, 3.41)	0.4955	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Weight decreased	Age (years)							0.2706
	<65	10/ 155 (6.5)	NE (NE , NE)	4/ 137 (2.9)	NE (NE , NE)	1.99 (0.62, 6.34)	0.2371	
	>=65	14/ 88 (15.9)	NE (NE , NE)	3/ 101 (3.0)	NE (NE , NE)	5.30 (1.52, 18.46)	0.0033	
	Sex							0.6193
	Male	15/ 139 (10.8)	NE (NE , NE)	5/ 135 (3.7)	NE (NE , NE)	2.72 (0.99, 7.49)	0.0443	
	Female	9/ 104 (8.7)	NE (NE , NE)	2/ 103 (1.9)	NE (NE , NE)	4.30 (0.93, 19.90)	0.0415	
	Disease Status 2L							0.3069
	2L: progression of disease <= 2 years	5/ 63 (7.9)	NE (NE , NE)	3/ 61 (4.9)	NE (NE , NE)	1.53 (0.37, 6.41)	0.5571	
	2L: progression of disease > 2 years	9/ 94 (9.6)	NE (NE , NE)	2/ 94 (2.1)	NE (NE , NE)	4.49 (0.97, 20.80)	0.0351	
	Disease Status 3L+							
	3L+: < 6 months	2/ 23 (8.7)		1/ 22 (4.5)				
	3L+: >= 6 months	8/ 63 (12.7)		1/ 61 (1.6)				
	Region							0.6360
	US/Western Europe	8/ 58 (13.8)	NE (NE , NE)	3/ 57 (5.3)	NE (NE , NE)	2.47 (0.66, 9.32)	0.1664	
	Rest of world	16/ 185 (8.6)	NE (NE , NE)	4/ 181 (2.2)	NE (NE , NE)	3.63 (1.21, 10.88)	0.0137	
	Number of prior anti-lymphoma therapies							0.5110
	2L	14/ 157 (8.9)	NE (NE , NE)	5/ 155 (3.2)	NE (NE , NE)	2.71 (0.97, 7.51)	0.0466	
	3L+	10/ 86 (11.6)	NE (NE , NE)	2/ 83 (2.4)	NE (NE , NE)	4.48 (0.98, 20.48)	0.0337	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders	Age (years)							0.5196
	<65	62/ 155 (40.0)	NE (NE , NE)	38/ 137 (27.7)	NE (NE , NE)	1.51 (1.01, 2.26)	0.0448	
	>=65	40/ 88 (45.5)	NE (6.80, NE)	28/ 101 (27.7)	NE (NE , NE)	1.77 (1.09, 2.88)	0.0186	
	Sex							0.8566
	Male	58/ 139 (41.7)	NE (11.30, NE)	35/ 135 (25.9)	NE (NE , NE)	1.65 (1.08, 2.51)	0.0185	
	Female	44/ 104 (42.3)	NE (5.55, NE)	31/ 103 (30.1)	NE (NE , NE)	1.55 (0.98, 2.46)	0.0575	
	Disease Status 2L							0.6231
	2L: progression of disease <= 2 years	27/ 63 (42.9)	NE (2.37, NE)	15/ 61 (24.6)	NE (NE , NE)	1.89 (1.01, 3.56)	0.0435	
	2L: progression of disease > 2 years	38/ 94 (40.4)	NE (9.20, NE)	27/ 94 (28.7)	NE (NE , NE)	1.50 (0.92, 2.46)	0.1033	
	Disease Status 3L+							0.4185
	3L+: < 6 months	11/ 23 (47.8)	NE (0.62, NE)	5/ 22 (22.7)	NE (NE , NE)	2.40 (0.83, 6.93)	0.0936	
	3L+: >= 6 months	26/ 63 (41.3)	NE (8.74, NE)	19/ 61 (31.1)	NE (NE , NE)	1.37 (0.76, 2.49)	0.2894	
	Region							0.8475
	US/Western Europe	23/ 58 (39.7)	NE (3.81, NE)	16/ 57 (28.1)	NE (NE , NE)	1.47 (0.78, 2.80)	0.2314	
	Rest of world	79/ 185 (42.7)	NE (11.30, NE)	50/ 181 (27.6)	NE (NE , NE)	1.64 (1.15, 2.33)	0.0057	
	Number of prior anti-lymphoma therapies							0.9726
	2L	65/ 157 (41.4)	NE (11.30, NE)	42/ 155 (27.1)	NE (NE , NE)	1.63 (1.11, 2.41)	0.0122	
	3L+	37/ 86 (43.0)	NE (8.34, NE)	24/ 83 (28.9)	NE (NE , NE)	1.57 (0.94, 2.62)	0.0840	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hypertriglyceridaemia	Age (years)							0.9873
	<65	17/ 155 (11.0)	NE (NE , NE)	7/ 137 (5.1)	NE (NE , NE)	2.07 (0.86, 5.00)	0.0968	
	>=65	3/ 88 (3.4)	NE (NE , NE)	0/ 101 (0.0)	NE (NE , NE)	NE		
	Sex							0.6390
	Male	11/ 139 (7.9)	NE (NE , NE)	3/ 135 (2.2)	NE (NE , NE)	3.24 (0.90, 11.66)	0.0567	
	Female	9/ 104 (8.7)	NE (NE , NE)	4/ 103 (3.9)	NE (NE , NE)	2.24 (0.69, 7.28)	0.1658	
	Disease Status 2L							0.7389
	2L: progression of disease <= 2 years	10/ 63 (15.9)	NE (NE , NE)	2/ 61 (3.3)	NE (NE , NE)	4.07 (0.88, 18.68)	0.0512	
	2L: progression of disease > 2 years	6/ 94 (6.4)	NE (NE , NE)	2/ 94 (2.1)	NE (NE , NE)	3.03 (0.61, 15.03)	0.1526	
	Disease Status 3L+							
	3L+: < 6 months	2/ 23 (8.7)		1/ 22 (4.5)				
	3L+: >= 6 months	2/ 63 (3.2)		2/ 61 (3.3)				
	Region							0.9909
	US/Western Europe	1/ 58 (1.7)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
	Rest of world	19/ 185 (10.3)	NE (NE , NE)	7/ 181 (3.9)	NE (NE , NE)	2.58 (1.08, 6.13)	0.0264	
	Number of prior anti-lymphoma therapies							0.2415
	2L	16/ 157 (10.2)	NE (NE , NE)	4/ 155 (2.6)	NE (NE , NE)	3.76 (1.26, 11.27)	0.0109	
	3L+	4/ 86 (4.7)	NE (NE , NE)	3/ 83 (3.6)	NE (NE , NE)	1.27 (0.28, 5.68)	0.7515	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Age (years)							0.6686
	<65	31/ 155 (20.0)	NE (NE , NE)	11/ 137 (8.0)	NE (NE , NE)	2.48 (1.25, 4.93)	0.0074	
	>=65	17/ 88 (19.3)	NE (NE , NE)	10/ 101 (9.9)	NE (NE , NE)	1.89 (0.86, 4.14)	0.1052	
	Sex							0.4836
	Male	25/ 139 (18.0)	NE (NE , NE)	12/ 135 (8.9)	NE (NE , NE)	1.85 (0.93, 3.69)	0.0762	
	Female	23/ 104 (22.1)	NE (NE , NE)	9/ 103 (8.7)	NE (NE , NE)	2.73 (1.26, 5.91)	0.0076	
	Disease Status 2L							0.3054
	2L: progression of disease <= 2 years	12/ 63 (19.0)	NE (NE , NE)	7/ 61 (11.5)	NE (NE , NE)	1.56 (0.61, 3.96)	0.3485	
	2L: progression of disease > 2 years	13/ 94 (13.8)	NE (NE , NE)	4/ 94 (4.3)	NE (NE , NE)	3.31 (1.08, 10.17)	0.0259	
	Disease Status 3L+							0.3109
	3L+: < 6 months	6/ 23 (26.1)	NE (NE , NE)	1/ 22 (4.5)	NE (NE , NE)	6.24 (0.75, 51.87)	0.0521	
	3L+: >= 6 months	17/ 63 (27.0)	NE (NE , NE)	9/ 61 (14.8)	NE (NE , NE)	1.81 (0.81, 4.08)	0.1433	
	Region							0.3309
	US/Western Europe	14/ 58 (24.1)	NE (NE , NE)	4/ 57 (7.0)	NE (NE , NE)	3.36 (1.10, 10.23)	0.0239	
	Rest of world	34/ 185 (18.4)	NE (NE , NE)	17/ 181 (9.4)	NE (NE , NE)	1.94 (1.08, 3.47)	0.0234	
	Number of prior anti-lymphoma therapies							0.9342
	2L	25/ 157 (15.9)	NE (NE , NE)	11/ 155 (7.1)	NE (NE , NE)	2.23 (1.10, 4.53)	0.0228	
	3L+	23/ 86 (26.7)	NE (NE , NE)	10/ 83 (12.0)	NE (NE , NE)	2.23 (1.06, 4.70)	0.0297	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders	Age (years)							0.2022
	<65	56/ 155 (36.1)	NE (NE , NE)	38/ 137 (27.7)	NE (NE , NE)	1.29 (0.86, 1.96)	0.2175	
	>=65	34/ 88 (38.6)	NE (5.22, NE)	21/ 101 (20.8)	NE (NE , NE)	2.08 (1.21, 3.58)	0.0069	
	Sex							0.8635
	Male	51/ 139 (36.7)	NE (NE , NE)	32/ 135 (23.7)	NE (NE , NE)	1.60 (1.03, 2.49)	0.0360	
	Female	39/ 104 (37.5)	NE (NE , NE)	27/ 103 (26.2)	NE (NE , NE)	1.50 (0.92, 2.45)	0.1019	
	Disease Status 2L							0.5810
	2L: progression of disease <= 2 years	21/ 63 (33.3)	NE (NE , NE)	12/ 61 (19.7)	NE (NE , NE)	1.67 (0.82, 3.40)	0.1526	
	2L: progression of disease > 2 years	35/ 94 (37.2)	NE (NE , NE)	28/ 94 (29.8)	NE (NE , NE)	1.32 (0.80, 2.17)	0.2692	
	Disease Status 3L+							0.1064
	3L+: < 6 months	5/ 23 (21.7)	NE (7.52, NE)	6/ 22 (27.3)	NE (7.06, NE)	0.75 (0.23, 2.46)	0.6301	
	3L+: >= 6 months	29/ 63 (46.0)	NE (4.34, NE)	13/ 61 (21.3)	NE (NE , NE)	2.37 (1.23, 4.56)	0.0075	
	Region							0.9154
	US/Western Europe	31/ 58 (53.4)	7.23 (1.77, NE)	20/ 57 (35.1)	NE (6.54, NE)	1.60 (0.91, 2.82)	0.0952	
	Rest of world	59/ 185 (31.9)	NE (NE , NE)	39/ 181 (21.5)	NE (NE , NE)	1.53 (1.02, 2.30)	0.0363	
	Number of prior anti-lymphoma therapies							0.4377
	2L	56/ 157 (35.7)	NE (NE , NE)	40/ 155 (25.8)	NE (NE , NE)	1.42 (0.95, 2.14)	0.0860	
	3L+	34/ 86 (39.5)	NE (7.95, NE)	19/ 83 (22.9)	NE (NE , NE)	1.85 (1.05, 3.24)	0.0289	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders, PT: Headache	Age (years)							0.1355
	<65	18/ 155 (11.6)	NE (NE , NE)	8/ 137 (5.8)	NE (NE , NE)	1.85 (0.80, 4.25)	0.1426	
	>=65	9/ 88 (10.2)	NE (NE , NE)	1/ 101 (1.0)	NE (NE , NE)	10.68 (1.35, 84.33)	0.0050	
	Sex							0.7617
	Male	14/ 139 (10.1)	NE (NE , NE)	4/ 135 (3.0)	NE (NE , NE)	3.23 (1.06, 9.82)	0.0289	
	Female	13/ 104 (12.5)	NE (NE , NE)	5/ 103 (4.9)	NE (NE , NE)	2.52 (0.90, 7.06)	0.0693	
	Disease Status 2L							0.4361
	2L: progression of disease <= 2 years	8/ 63 (12.7)	NE (NE , NE)	2/ 61 (3.3)	NE (NE , NE)	3.69 (0.78, 17.40)	0.0770	
	2L: progression of disease > 2 years	9/ 94 (9.6)	NE (NE , NE)	5/ 94 (5.3)	NE (NE , NE)	1.74 (0.58, 5.20)	0.3122	
	Disease Status 3L+							0.9997
	3L+: < 6 months	0/ 23 (0.0)	NE (NE , NE)	0/ 22 (0.0)	NE (NE , NE)	NE		
	3L+: >= 6 months	10/ 63 (15.9)	NE (NE , NE)	2/ 61 (3.3)	NE (NE , NE)	4.78 (1.05, 21.84)	0.0257	
	Region							0.6883
	US/Western Europe	11/ 58 (19.0)	NE (NE , NE)	3/ 57 (5.3)	NE (NE , NE)	3.38 (0.94, 12.13)	0.0469	
	Rest of world	16/ 185 (8.6)	NE (NE , NE)	6/ 181 (3.3)	NE (NE , NE)	2.54 (0.99, 6.50)	0.0435	
	Number of prior anti-lymphoma therapies							0.4007
	2L	17/ 157 (10.8)	NE (NE , NE)	7/ 155 (4.5)	NE (NE , NE)	2.30 (0.95, 5.55)	0.0559	
	3L+	10/ 86 (11.6)	NE (NE , NE)	2/ 83 (2.4)	NE (NE , NE)	4.69 (1.03, 21.44)	0.0279	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Nervous system disorders, PT: Tremor	Age (years)							0.9886
	<65	13/ 155 (8.4)	NE (NE , NE)	2/ 137 (1.5)	NE (NE , NE)	5.82 (1.31, 25.78)	0.0085	
	>=65	7/ 88 (8.0)	NE (NE , NE)	0/ 101 (0.0)	NE (NE , NE)	NE		
	Sex							0.9886
	Male	12/ 139 (8.6)	NE (NE , NE)	2/ 135 (1.5)	NE (NE , NE)	5.94 (1.33, 26.55)	0.0079	
	Female	8/ 104 (7.7)	NE (NE , NE)	0/ 103 (0.0)	NE (NE , NE)	NE		
	Disease Status 2L							0.9893
	2L: progression of disease <= 2 years	3/ 63 (4.8)	NE (NE , NE)	1/ 61 (1.6)	NE (NE , NE)	2.71 (0.28, 26.05)	0.3691	
	2L: progression of disease > 2 years	11/ 94 (11.7)	NE (NE , NE)	0/ 94 (0.0)	NE (NE , NE)	NE		
	Disease Status 3L+							
	3L+: < 6 months	1/ 23 (4.3)		0/ 22 (0.0)				
	3L+: >= 6 months	5/ 63 (7.9)		1/ 61 (1.6)				
	Region							0.9918
	US/Western Europe	7/ 58 (12.1)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
	Rest of world	13/ 185 (7.0)	NE (NE , NE)	2/ 181 (1.1)	NE (NE , NE)	6.51 (1.47, 28.86)	0.0044	
	Number of prior anti-lymphoma therapies							0.5658
	2L	14/ 157 (8.9)	NE (NE , NE)	1/ 155 (0.6)	NE (NE , NE)	14.11 (1.86, 107.26)	0.0007	
	3L+	6/ 86 (7.0)	NE (NE , NE)	1/ 83 (1.2)	NE (NE , NE)	5.96 (0.72, 49.47)	0.0600	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Psychiatric disorders	Age (years)							0.4214
	<65	27/ 155 (17.4)	NE (NE , NE)	9/ 137 (6.6)	NE (NE , NE)	2.72 (1.28, 5.80)	0.0066	
	>=65	19/ 88 (21.6)	NE (NE , NE)	5/ 101 (5.0)	NE (NE , NE)	4.59 (1.71, 12.30)	0.0008	
	Sex							0.5872
	Male	24/ 139 (17.3)	NE (NE , NE)	6/ 135 (4.4)	NE (NE , NE)	3.91 (1.60, 9.57)	0.0013	
	Female	22/ 104 (21.2)	NE (NE , NE)	8/ 103 (7.8)	NE (NE , NE)	2.89 (1.29, 6.50)	0.0069	
	Disease Status 2L							0.2030
	2L: progression of disease <= 2 years	5/ 63 (7.9)	NE (NE , NE)	4/ 61 (6.6)	NE (NE , NE)	1.12 (0.30, 4.19)	0.8663	
	2L: progression of disease > 2 years	16/ 94 (17.0)	NE (NE , NE)	5/ 94 (5.3)	NE (NE , NE)	3.26 (1.19, 8.91)	0.0144	
	Disease Status 3L+							0.9724
	3L+: < 6 months	5/ 23 (21.7)	NE (NE , NE)	1/ 22 (4.5)	NE (NE , NE)	5.43 (0.63, 46.55)	0.0829	
	3L+: >= 6 months	20/ 63 (31.7)	NE (NE , NE)	4/ 61 (6.6)	NE (NE , NE)	5.41 (1.85, 15.83)	0.0005	
	Region							0.9022
	US/Western Europe	14/ 58 (24.1)	NE (NE , NE)	4/ 57 (7.0)	NE (NE , NE)	3.46 (1.14, 10.51)	0.0195	
	Rest of world	32/ 185 (17.3)	NE (NE , NE)	10/ 181 (5.5)	NE (NE , NE)	3.28 (1.61, 6.67)	0.0005	
	Number of prior anti-lymphoma therapies							0.1747
	2L	21/ 157 (13.4)	NE (NE , NE)	9/ 155 (5.8)	NE (NE , NE)	2.26 (1.03, 4.94)	0.0351	
	3L+	25/ 86 (29.1)	NE (NE , NE)	5/ 83 (6.0)	NE (NE , NE)	5.39 (2.06, 14.10)	0.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Psychiatric disorders, PT: Insomnia	Age (years)							0.2183
	<65	20/ 155 (12.9)	NE (NE , NE)	6/ 137 (4.4)	NE (NE , NE)	3.05 (1.22, 7.59)	0.0117	
	>=65	15/ 88 (17.0)	NE (NE , NE)	2/ 101 (2.0)	NE (NE , NE)	8.97 (2.05, 39.23)	0.0004	
	Sex							0.6545
	Male	19/ 139 (13.7)	NE (NE , NE)	5/ 135 (3.7)	NE (NE , NE)	3.79 (1.41, 10.16)	0.0043	
	Female	16/ 104 (15.4)	NE (NE , NE)	3/ 103 (2.9)	NE (NE , NE)	5.50 (1.60, 18.86)	0.0023	
	Disease Status 2L							0.1059
	2L: progression of disease <= 2 years	4/ 63 (6.3)	NE (NE , NE)	4/ 61 (6.6)	NE (NE , NE)	0.94 (0.23, 3.76)	0.9302	
	2L: progression of disease > 2 years	10/ 94 (10.6)	NE (NE , NE)	2/ 94 (2.1)	NE (NE , NE)	5.10 (1.12, 23.27)	0.0190	
	Disease Status 3L+							0.4260
	3L+: < 6 months	5/ 23 (21.7)	NE (NE , NE)	1/ 22 (4.5)	NE (NE , NE)	5.43 (0.63, 46.55)	0.0829	
	3L+: >= 6 months	16/ 63 (25.4)	NE (NE , NE)	1/ 61 (1.6)	NE (NE , NE)	17.00 (2.26, 128.18)	0.0002	
	Region							0.3611
	US/Western Europe	10/ 58 (17.2)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	10.10 (1.29, 78.91)	0.0063	
	Rest of world	25/ 185 (13.5)	NE (NE , NE)	7/ 181 (3.9)	NE (NE , NE)	3.62 (1.56, 8.37)	0.0013	
	Number of prior anti-lymphoma therapies							0.0729
	2L	14/ 157 (8.9)	NE (NE , NE)	6/ 155 (3.9)	NE (NE , NE)	2.31 (0.89, 6.01)	0.0776	
	3L+	21/ 86 (24.4)	NE (NE , NE)	2/ 83 (2.4)	NE (NE , NE)	11.20 (2.63, 47.80)	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders	Age (years)							0.9937
	<65	60/ 155 (38.7)	NE (12.45, NE)	33/ 137 (24.1)	NE (NE , NE)	1.53 (1.00, 2.34)	0.0478	
	>=65	38/ 88 (43.2)	NE (7.39, NE)	28/ 101 (27.7)	NE (NE , NE)	1.53 (0.94, 2.50)	0.0863	
	Sex							0.5490
	Male	59/ 139 (42.4)	NE (10.28, NE)	33/ 135 (24.4)	NE (NE , NE)	1.63 (1.06, 2.50)	0.0234	
	Female	39/ 104 (37.5)	NE (12.45, NE)	28/ 103 (27.2)	NE (NE , NE)	1.35 (0.83, 2.20)	0.2221	
	Disease Status 2L							0.8578
	2L: progression of disease <= 2 years	22/ 63 (34.9)	NE (11.17, NE)	12/ 61 (19.7)	NE (NE , NE)	1.57 (0.77, 3.18)	0.2065	
	2L: progression of disease > 2 years	38/ 94 (40.4)	NE (9.26, NE)	26/ 94 (27.7)	NE (NE , NE)	1.46 (0.89, 2.41)	0.1326	
	Disease Status 3L+							0.0175
	3L+: < 6 months	6/ 23 (26.1)	NE (12.35, NE)	8/ 22 (36.4)	NE (1.41, NE)	0.48 (0.16, 1.48)	0.1934	
	3L+: >= 6 months	32/ 63 (50.8)	11.63 (6.83, NE)	15/ 61 (24.6)	NE (NE , NE)	2.21 (1.20, 4.09)	0.0092	
	Region							0.3145
	US/Western Europe	28/ 58 (48.3)	NE (5.45, NE)	21/ 57 (36.8)	NE (7.59, NE)	1.19 (0.67, 2.09)	0.5515	
	Rest of world	70/ 185 (37.8)	NE (12.45, NE)	40/ 181 (22.1)	NE (NE , NE)	1.67 (1.13, 2.46)	0.0093	
	Number of prior anti-lymphoma therapies							0.8315
	2L	60/ 157 (38.2)	NE (NE , NE)	38/ 155 (24.5)	NE (NE , NE)	1.49 (0.99, 2.24)	0.0522	
	3L+	38/ 86 (44.2)	12.45 (10.22, NE)	23/ 83 (27.7)	NE (NE , NE)	1.53 (0.91, 2.57)	0.1073	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Age (years)							0.4529
	<65	31/ 155 (20.0)	NE (NE , NE)	17/ 137 (12.4)	NE (NE , NE)	1.42 (0.78, 2.57)	0.2454	
	>=65	16/ 88 (18.2)	NE (NE , NE)	8/ 101 (7.9)	NE (NE , NE)	2.13 (0.91, 4.97)	0.0745	
	Sex							0.2925
	Male	30/ 139 (21.6)	NE (NE , NE)	12/ 135 (8.9)	NE (NE , NE)	2.09 (1.07, 4.09)	0.0272	
	Female	17/ 104 (16.3)	NE (NE , NE)	13/ 103 (12.6)	NE (NE , NE)	1.23 (0.59, 2.53)	0.5813	
	Disease Status 2L							0.7522
	2L: progression of disease <= 2 years	12/ 63 (19.0)	NE (NE , NE)	5/ 61 (8.2)	NE (NE , NE)	1.84 (0.65, 5.25)	0.2459	
	2L: progression of disease > 2 years	19/ 94 (20.2)	NE (NE , NE)	12/ 94 (12.8)	NE (NE , NE)	1.49 (0.72, 3.07)	0.2755	
	Disease Status 3L+							0.1628
	3L+: < 6 months	1/ 23 (4.3)	NE (NE , NE)	2/ 22 (9.1)	NE (NE , NE)	0.48 (0.04, 5.27)	0.5370	
	3L+: >= 6 months	15/ 63 (23.8)	NE (NE , NE)	6/ 61 (9.8)	NE (NE , NE)	2.30 (0.89, 5.94)	0.0767	
	Region							0.7187
	US/Western Europe	15/ 58 (25.9)	NE (NE , NE)	7/ 57 (12.3)	NE (NE , NE)	1.93 (0.79, 4.74)	0.1426	
	Rest of world	32/ 185 (17.3)	NE (NE , NE)	18/ 181 (9.9)	NE (NE , NE)	1.55 (0.87, 2.77)	0.1333	
	Number of prior anti-lymphoma therapies							0.7799
	2L	31/ 157 (19.7)	NE (NE , NE)	17/ 155 (11.0)	NE (NE , NE)	1.59 (0.88, 2.88)	0.1199	
	3L+	16/ 86 (18.6)	NE (NE , NE)	8/ 83 (9.6)	NE (NE , NE)	1.77 (0.75, 4.15)	0.1836	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain	Age (years)							
	<65	6/ 155 (3.9)		1/ 137 (0.7)				
	>=65	5/ 88 (5.7)		1/ 101 (1.0)				
	Sex							
	Male	6/ 139 (4.3)		1/ 135 (0.7)				
	Female	5/ 104 (4.8)		1/ 103 (1.0)				
	Disease Status 2L							
	2L: progression of disease <= 2 years	3/ 63 (4.8)		0/ 61 (0.0)				
	2L: progression of disease > 2 years	3/ 94 (3.2)		1/ 94 (1.1)				
	Disease Status 3L+							
	3L+: < 6 months	0/ 23 (0.0)		0/ 22 (0.0)				
	3L+: >= 6 months	5/ 63 (7.9)		1/ 61 (1.6)				
	Region							
	US/Western Europe	4/ 58 (6.9)		1/ 57 (1.8)				
	Rest of world	7/ 185 (3.8)		1/ 181 (0.6)				
	Number of prior anti-lymphoma therapies							
	2L	6/ 157 (3.8)		1/ 155 (0.6)				
	3L+	5/ 86 (5.8)		1/ 83 (1.2)				

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.1.S Time to first frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Hypotension	Age (years)							
	<65	7/ 155 (4.5)		1/ 137 (0.7)				
	>=65	7/ 88 (8.0)		2/ 101 (2.0)				
	Sex							0.9925
	Male	6/ 139 (4.3)	NE (NE , NE)	0/ 135 (0.0)	NE (NE , NE)	NE		
	Female	8/ 104 (7.7)	NE (NE , NE)	3/ 103 (2.9)	NE (NE , NE)	2.70 (0.72, 10.18)	0.1261	
	Disease Status 2L							
	2L: progression of disease <= 2 years	4/ 63 (6.3)		1/ 61 (1.6)				
	2L: progression of disease > 2 years	5/ 94 (5.3)		1/ 94 (1.1)				
	Disease Status 3L+							
	3L+: < 6 months	0/ 23 (0.0)		0/ 22 (0.0)				
	3L+: >= 6 months	5/ 63 (7.9)		1/ 61 (1.6)				
	Region							0.7625
	US/Western Europe	6/ 58 (10.3)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	5.72 (0.69, 47.52)	0.0674	
	Rest of world	8/ 185 (4.3)	NE (NE , NE)	2/ 181 (1.1)	NE (NE , NE)	3.92 (0.83, 18.47)	0.0620	
	Number of prior anti-lymphoma therapies							0.9463
	2L	9/ 157 (5.7)	NE (NE , NE)	2/ 155 (1.3)	NE (NE , NE)	4.39 (0.95, 20.33)	0.0387	
	3L+	5/ 86 (5.8)	NE (NE , NE)	1/ 83 (1.2)	NE (NE , NE)	4.84 (0.57, 41.39)	0.1109	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders	Number of subjects with events, n/N (%)	19/243 (7.8)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.78 (0.83, 3.83)	
	p-value	0.1350	
	Relative Risk (95% CI)	1.86 (0.88, 3.92)	
	p-value	0.1021	
	Odds Ratio (95% CI)	1.93 (0.88, 4.25)	
	p-value	0.1007	
	Risk Difference (95% CI)	0.04 (-0.01, 0.08)	
	p-value	0.0937	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Febrile neutropenia	Number of subjects with events, n/N (%)	13/243 (5.3)	5/238 (2.1)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.36 (0.84, 6.63)	
	p-value	0.0926	
	Relative Risk (95% CI)	2.55 (0.92, 7.03)	
	p-value	0.0713	
	Odds Ratio (95% CI)	2.63 (0.92, 7.51)	
	p-value	0.0699	
	Risk Difference (95% CI)	0.03 (-0.00, 0.07)	
	p-value	0.0585	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions	Number of subjects with events, n/N (%)	13/243 (5.3)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.20 (0.53, 2.75)	
	p-value	0.6599	
	Relative Risk (95% CI)	1.27 (0.57, 2.85)	
	p-value	0.5563	
	Odds Ratio (95% CI)	1.29 (0.55, 3.00)	
	p-value	0.5561	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.5546	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Immune system disorders	Number of subjects with events, n/N (%)	47/243 (19.3)	1/238 (0.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (13.04, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	49.03 (6.77, 355.22)	
	p-value	<.0001	
	Relative Risk (95% CI)	46.03 (6.40, 330.95)	
	p-value	0.0001	
	Odds Ratio (95% CI)	56.83 (7.77, 415.64)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.19 (0.14, 0.24)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Immune system disorders, PT: Cytokine release syndrome	Number of subjects with events, n/N (%)	45/243 (18.5)	1/238 (0.4)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	47.90 (6.61, 347.25)	
	p-value	<.0001	
	Relative Risk (95% CI)	44.07 (6.12, 317.16)	
	p-value	0.0002	
	Odds Ratio (95% CI)	53.86 (7.36, 394.27)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.18 (0.13, 0.23)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations	Number of subjects with events, n/N (%)	81/243 (33.3)	35/238 (14.7)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	6.97 (3.68, 9.99)	12.94 (12.94, NE)
	Median (95% CI)	NE (13.73, NE)	NE (12.94, NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.19 (1.47, 3.26)	
	p-value	<.0001	
	Relative Risk (95% CI)	2.27 (1.59, 3.23)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.90 (1.85, 4.53)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.19 (0.11, 0.26)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: COVID-19	Number of subjects with events, n/N (%)	11/243 (4.5)	5/238 (2.1)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.90 (0.66, 5.48)	
	p-value	0.2258	
	Relative Risk (95% CI)	2.15 (0.76, 6.11)	
	p-value	0.1487	
	Odds Ratio (95% CI)	2.21 (0.76, 6.46)	
	p-value	0.1475	
	Risk Difference (95% CI)	0.02 (-0.01, 0.06)	
	p-value	0.1356	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n/N (%)	25/243 (10.3)	12/238 (5.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.82 (0.91, 3.63)	
	p-value	0.0839	
	Relative Risk (95% CI)	2.04 (1.05, 3.97)	
	p-value	0.0355	
	Odds Ratio (95% CI)	2.16 (1.06, 4.41)	
	p-value	0.0343	
	Risk Difference (95% CI)	0.05 (0.01, 0.10)	
	p-value	0.0295	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations	Number of subjects with events, n/N (%)	12/243 (4.9)	2/238 (0.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (14.88, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	4.84 (1.07, 22.01)	
	p-value	0.0240	
	Relative Risk (95% CI)	5.88 (1.33, 25.98)	
	p-value	0.0195	
	Odds Ratio (95% CI)	6.13 (1.36, 27.69)	
	p-value	0.0184	
	Risk Difference (95% CI)	0.04 (0.01, 0.07)	
	p-value	0.0067	

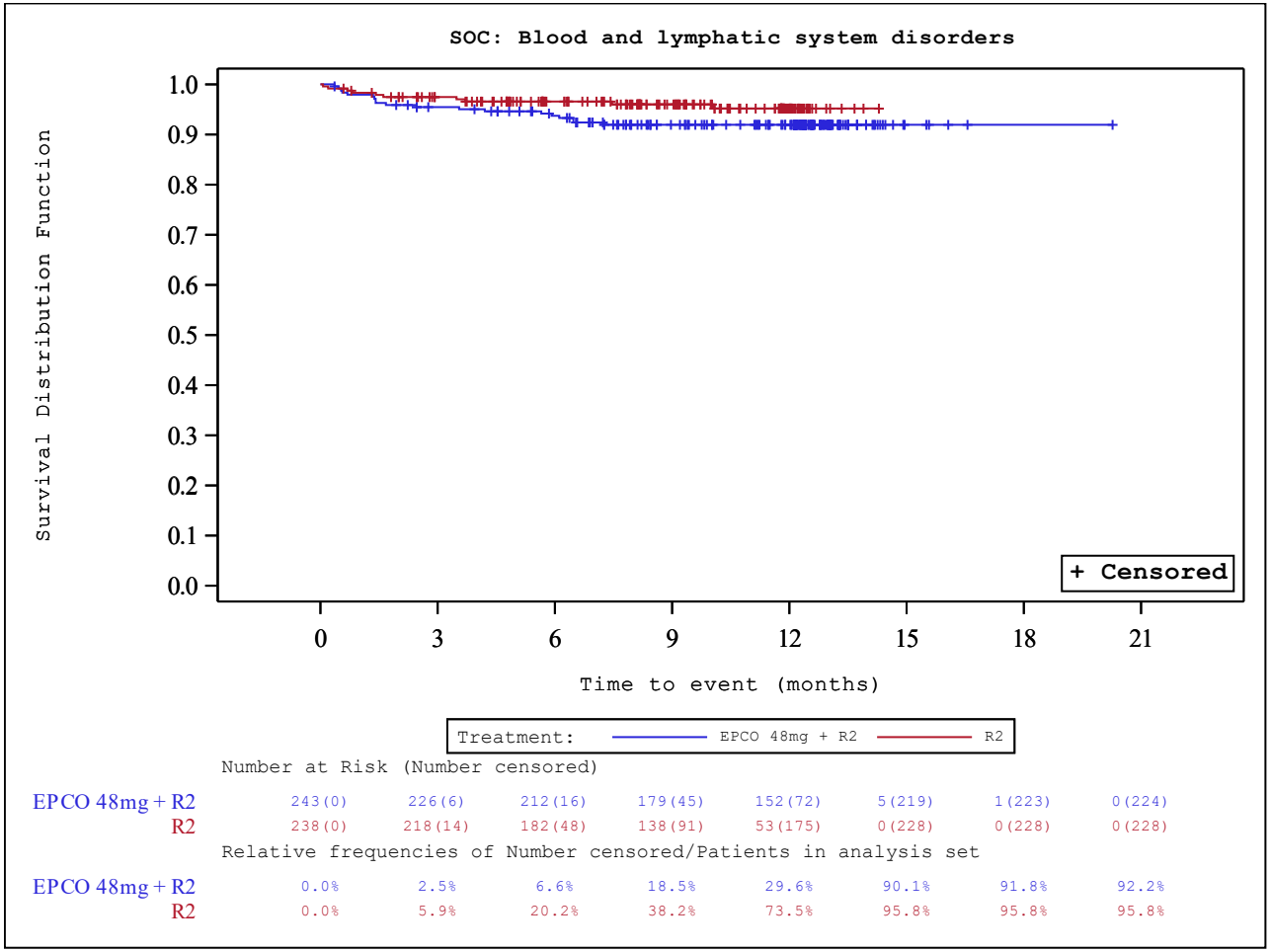
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.2 Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n/N (%)	5/243 (2.1)	13/238 (5.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.34 (0.12, 0.97)	
	p-value	0.0341	
	Relative Risk (95% CI)	0.38 (0.14, 1.04)	
	p-value	0.0596	
	Odds Ratio (95% CI)	0.36 (0.13, 1.04)	
	p-value	0.0583	
	Risk Difference (95% CI)	-0.03 (-0.07, -0.00)	
	p-value	0.0493	

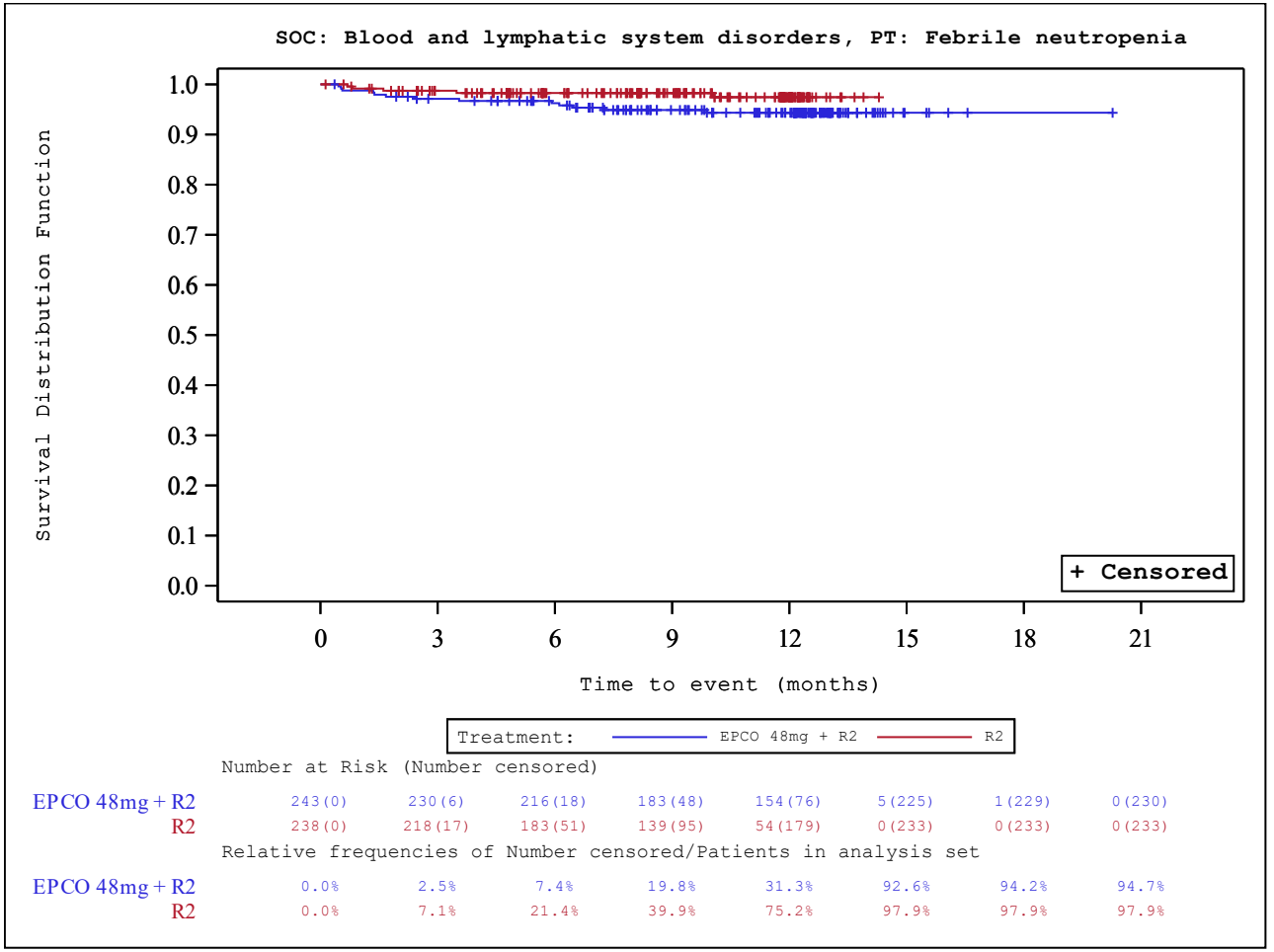
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



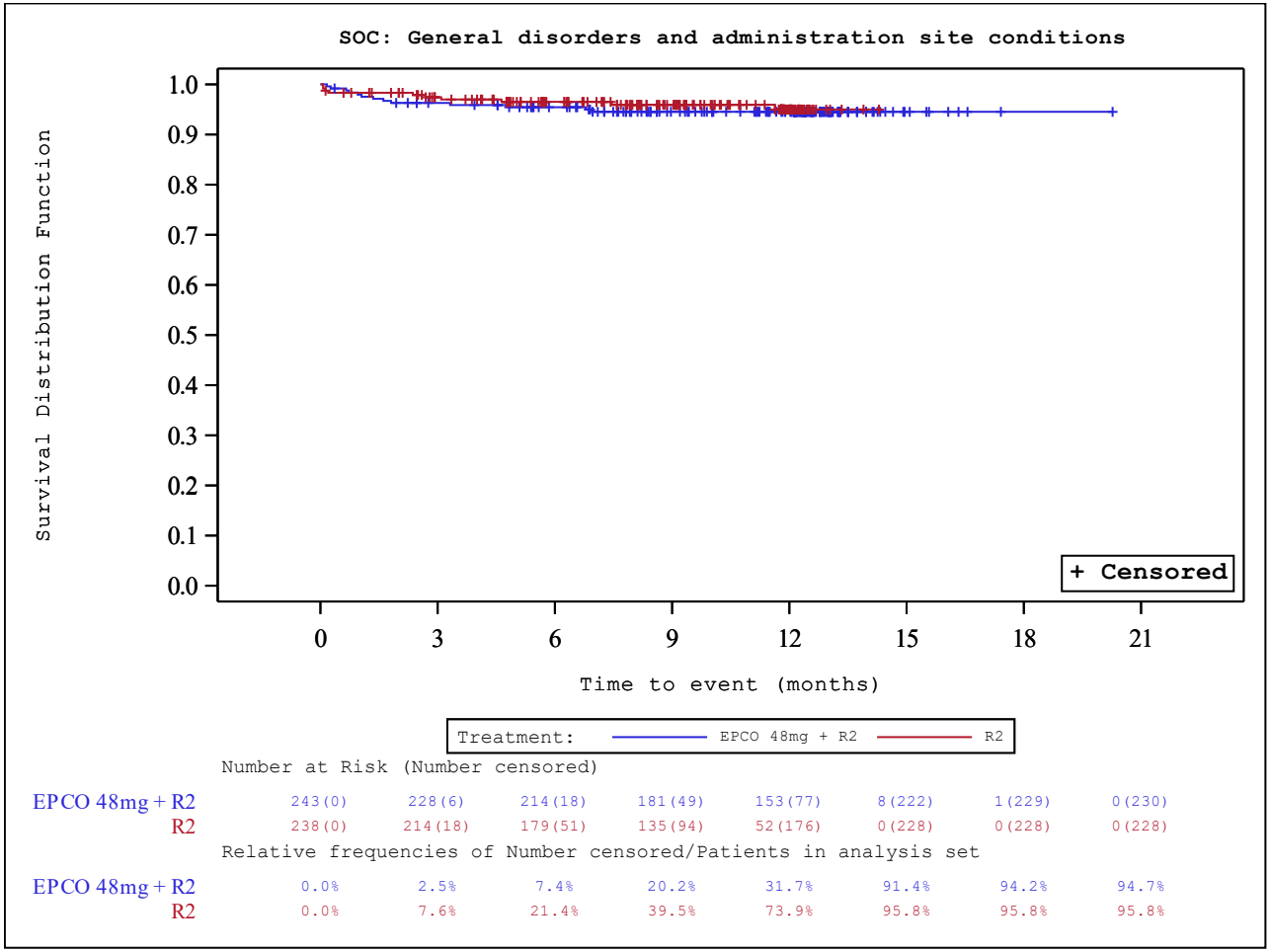
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



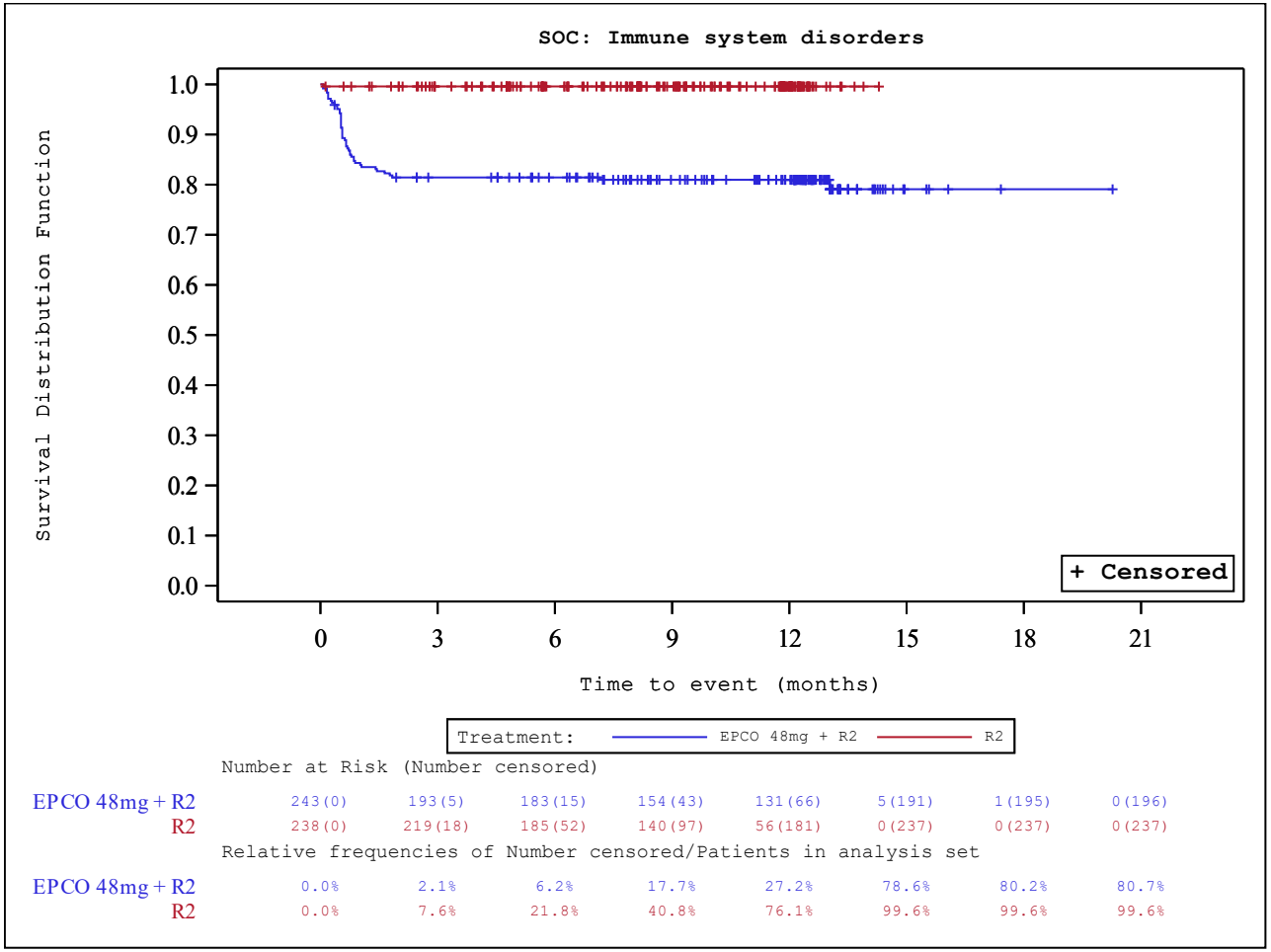
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



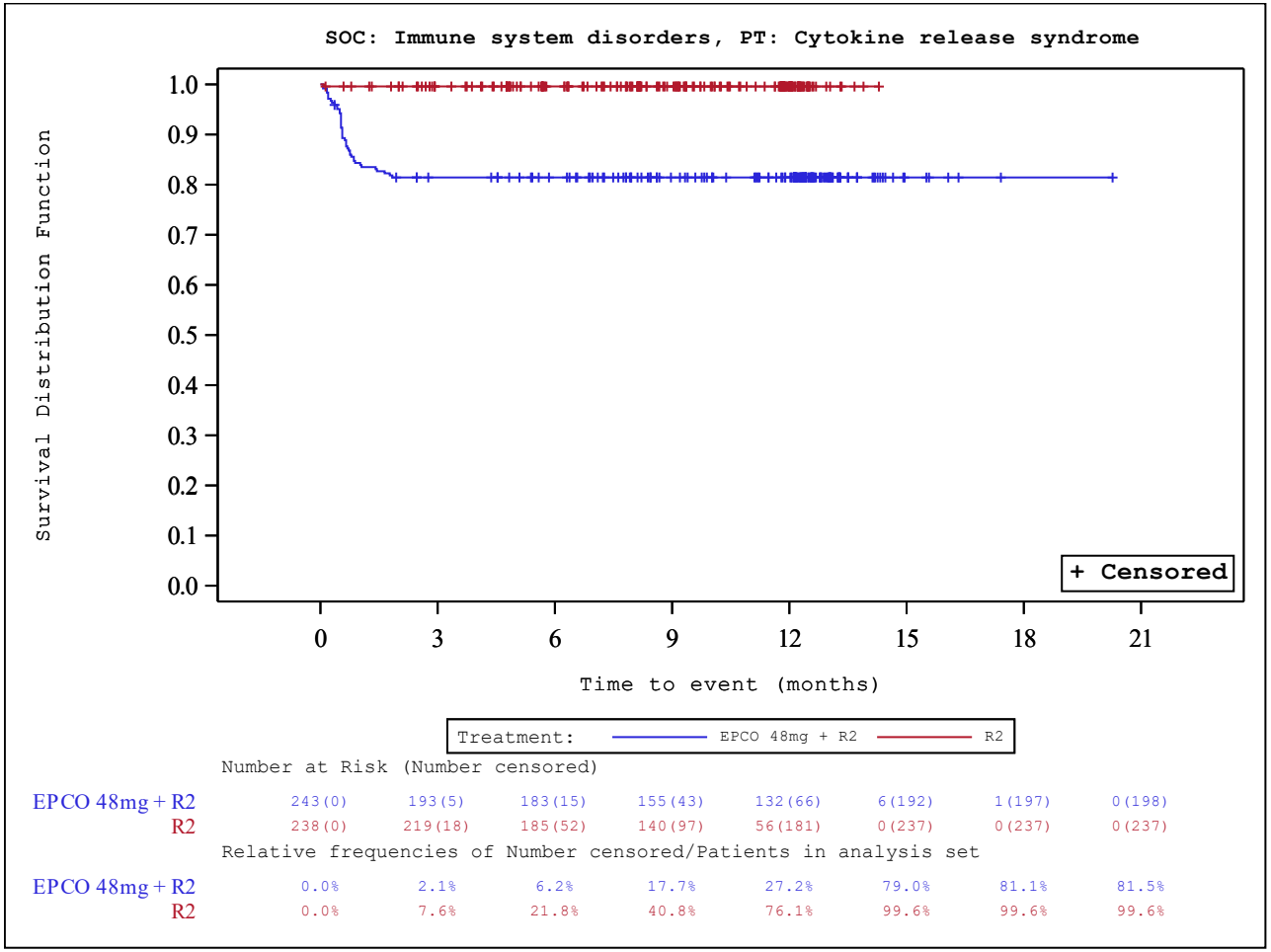
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



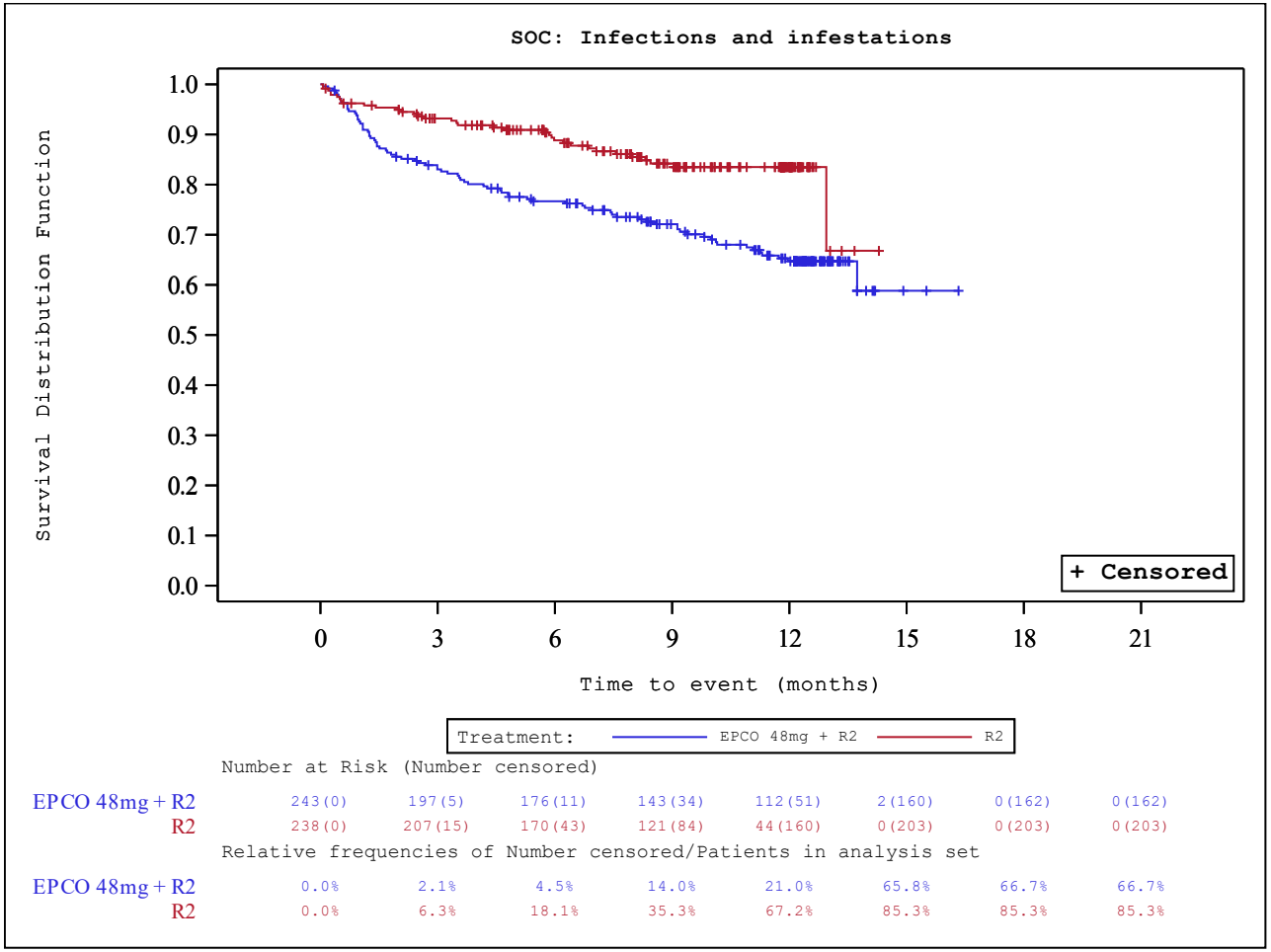
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



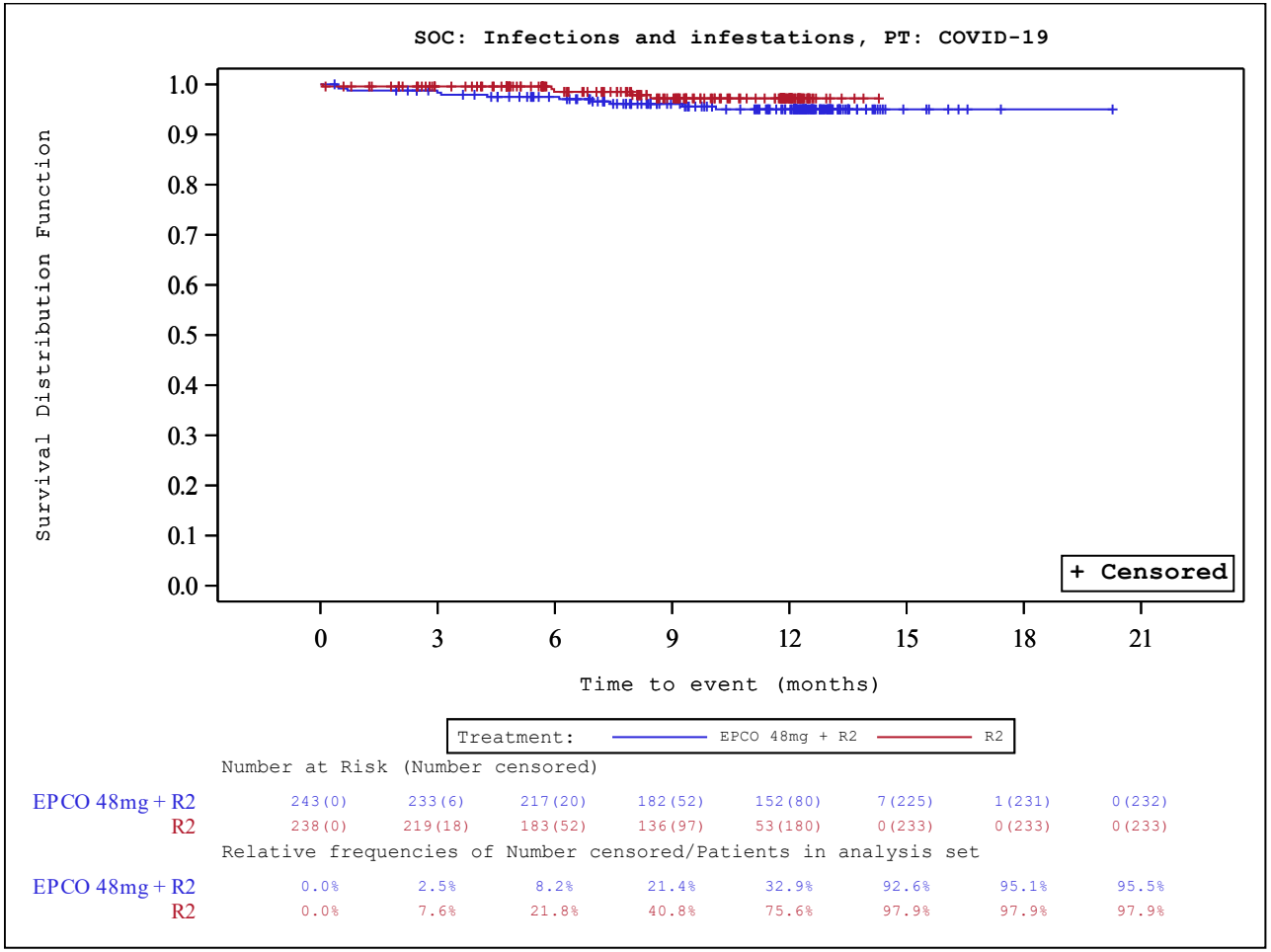
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



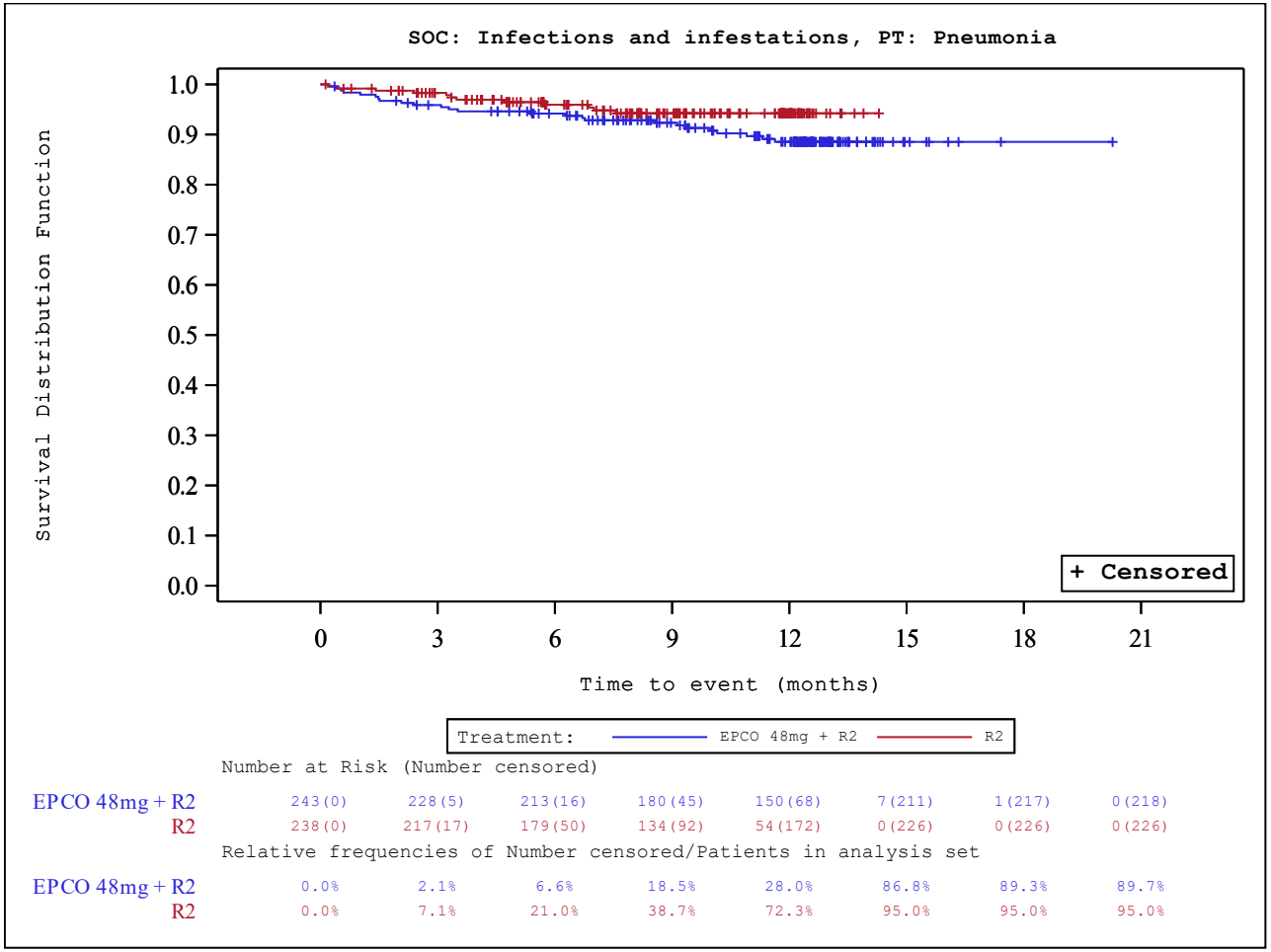
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



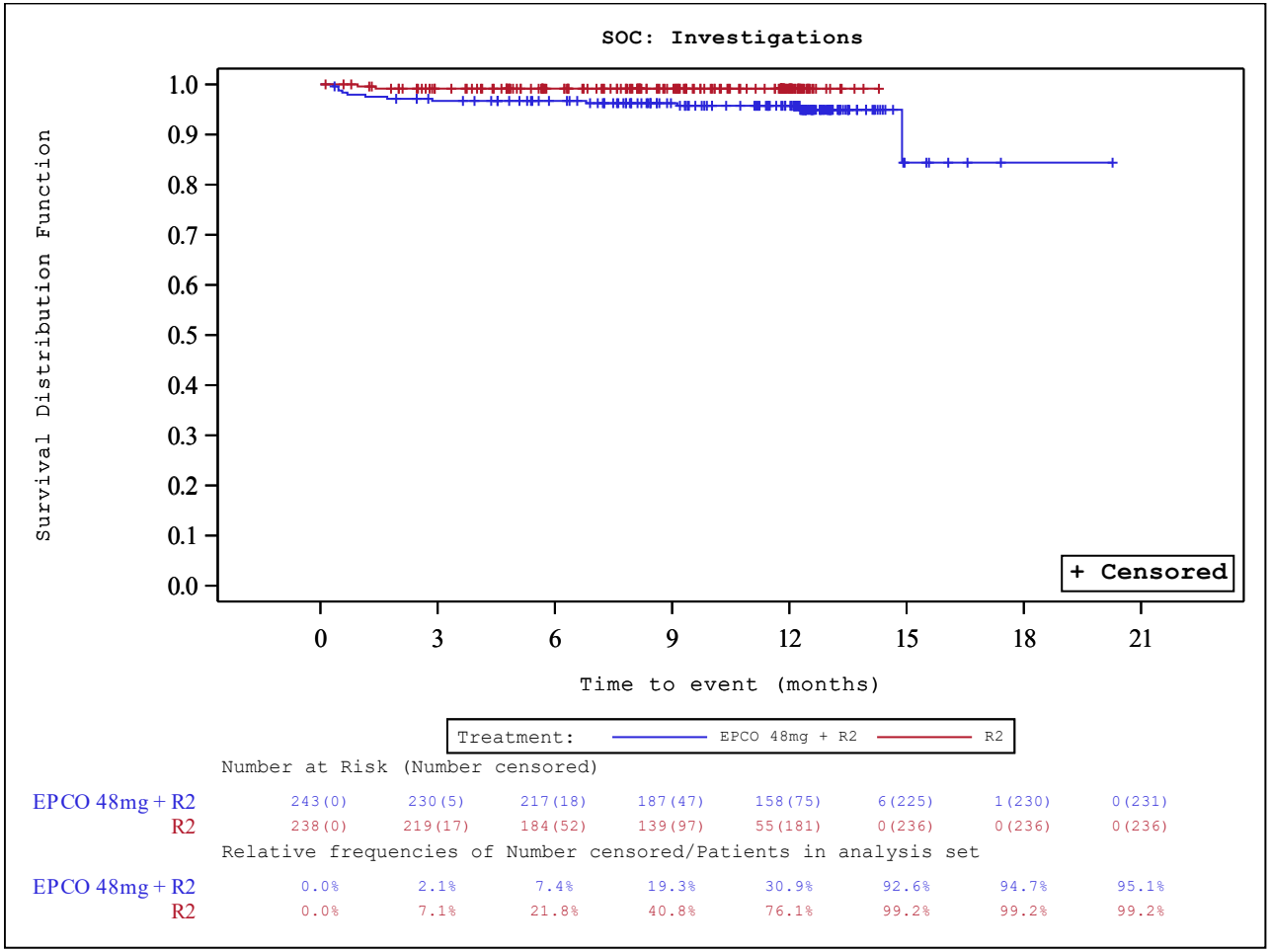
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



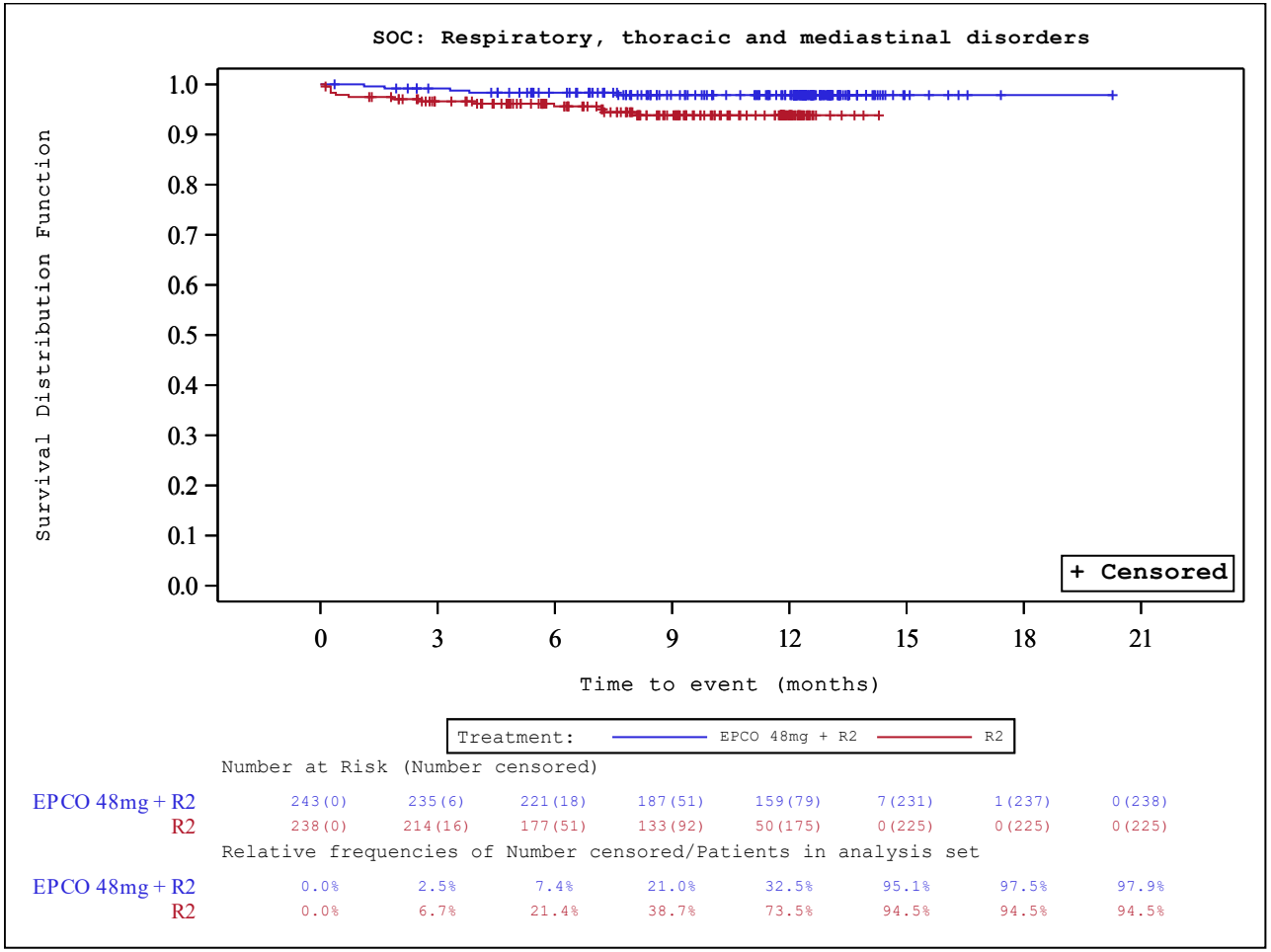
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.2 Kaplan-Meier Plot of Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.2.S Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders	Age (years)							0.9832
	<65	29/ 155 (18.7)	NE (NE , NE)	0/ 137 (0.0)	NE (NE , NE)	NE		
	>=65	18/ 88 (20.5)	NE (NE , NE)	1/ 101 (1.0)	NE (NE , NE)	22.47 (3.00, 168.34)	<.0001	
	Sex							0.9868
	Male	19/ 139 (13.7)	NE (NE , NE)	1/ 135 (0.7)	NE (NE , NE)	18.44 (2.46, 138.11)	<.0001	
	Female	28/ 104 (26.9)	NE (NE , NE)	0/ 103 (0.0)	NE (NE , NE)	NE		
	Disease Status 2L							0.9878
	2L: progression of disease <= 2 years	15/ 63 (23.8)	NE (NE , NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
	2L: progression of disease > 2 years	20/ 94 (21.3)	NE (NE , NE)	1/ 94 (1.1)	NE (NE , NE)	22.05 (2.96, 164.33)	<.0001	
	Disease Status 3L+							
	3L+: < 6 months	3/ 23 (13.0)		0/ 22 (0.0)				
	3L+: >= 6 months	9/ 63 (14.3)		0/ 61 (0.0)				
	Region							0.9873
	US/Western Europe	14/ 58 (24.1)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	14.90 (1.96, 113.29)	0.0005	
	Rest of world	33/ 185 (17.8)	NE (NE , NE)	0/ 181 (0.0)	NE (NE , NE)	NE		
	Number of prior anti-lymphoma therapies							0.9880
	2L	35/ 157 (22.3)	NE (NE , NE)	1/ 155 (0.6)	NE (NE , NE)	36.83 (5.04, 269.00)	<.0001	
	3L+	12/ 86 (14.0)	NE (NE , NE)	0/ 83 (0.0)	NE (NE , NE)	NE		

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.2.S Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders, PT: Cytokine release syndrome	Age (years)							0.9891
	<65	28/ 155 (18.1)	NE (NE , NE)	0/ 137 (0.0)	NE (NE , NE)	NE		
	>=65	17/ 88 (19.3)	NE (NE , NE)	1/ 101 (1.0)	NE (NE , NE)	21.28 (2.83, 159.82)	<.0001	
	Sex							0.9871
	Male	18/ 139 (12.9)	NE (NE , NE)	1/ 135 (0.7)	NE (NE , NE)	18.37 (2.45, 137.64)	<.0001	
	Female	27/ 104 (26.0)	NE (NE , NE)	0/ 103 (0.0)	NE (NE , NE)	NE		
	Disease Status 2L							0.9881
	2L: progression of disease <= 2 years	13/ 63 (20.6)	NE (NE , NE)	0/ 61 (0.0)	NE (NE , NE)	NE		
	2L: progression of disease > 2 years	20/ 94 (21.3)	NE (NE , NE)	1/ 94 (1.1)	NE (NE , NE)	22.05 (2.96, 164.33)	<.0001	
	Disease Status 3L+							
	3L+: < 6 months	3/ 23 (13.0)		0/ 22 (0.0)				
	3L+: >= 6 months	9/ 63 (14.3)		0/ 61 (0.0)				
	Region							0.9877
	US/Western Europe	14/ 58 (24.1)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	14.90 (1.96, 113.29)	0.0005	
	Rest of world	31/ 185 (16.8)	NE (NE , NE)	0/ 181 (0.0)	NE (NE , NE)	NE		
	Number of prior anti-lymphoma therapies							0.9881
	2L	33/ 157 (21.0)	NE (NE , NE)	1/ 155 (0.6)	NE (NE , NE)	35.75 (4.89, 261.39)	<.0001	
	3L+	12/ 86 (14.0)	NE (NE , NE)	0/ 83 (0.0)	NE (NE , NE)	NE		

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.2.S Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	Age (years)							0.5081
	<65	50/ 155 (32.3)	NE (NE , NE)	17/ 137 (12.4)	12.94 (NE , NE)	2.52 (1.45, 4.37)	0.0007	
	>=65	31/ 88 (35.2)	13.73 (13.73, NE)	18/ 101 (17.8)	NE (NE , NE)	1.92 (1.07, 3.44)	0.0252	
	Sex							0.8750
	Male	45/ 139 (32.4)	NE (13.73, NE)	19/ 135 (14.1)	NE (NE , NE)	2.11 (1.23, 3.62)	0.0054	
	Female	36/ 104 (34.6)	NE (NE , NE)	16/ 103 (15.5)	NE (12.94, NE)	2.29 (1.27, 4.13)	0.0047	
	Disease Status 2L							0.2271
	2L: progression of disease <= 2 years	15/ 63 (23.8)	NE (NE , NE)	9/ 61 (14.8)	NE (NE , NE)	1.32 (0.57, 3.04)	0.5127	
	2L: progression of disease > 2 years	29/ 94 (30.9)	NE (NE , NE)	11/ 94 (11.7)	NE (NE , NE)	2.67 (1.33, 5.35)	0.0039	
	Disease Status 3L+							0.8246
	3L+: < 6 months	10/ 23 (43.5)	13.73 (2.99, 13.73)	4/ 22 (18.2)	NE (8.44, NE)	2.27 (0.70, 7.41)	0.1595	
	3L+: >= 6 months	27/ 63 (42.9)	NE (8.57, NE)	11/ 61 (18.0)	NE (12.94, NE)	2.58 (1.28, 5.20)	0.0061	
	Region							0.1189
	US/Western Europe	18/ 58 (31.0)	NE (NE , NE)	12/ 57 (21.1)	NE (NE , NE)	1.42 (0.68, 2.94)	0.3482	
	Rest of world	63/ 185 (34.1)	NE (13.73, NE)	23/ 181 (12.7)	NE (12.94, NE)	2.61 (1.61, 4.21)	<.0001	
	Number of prior anti-lymphoma therapies							0.5353
	2L	44/ 157 (28.0)	NE (NE , NE)	20/ 155 (12.9)	NE (NE , NE)	2.05 (1.21, 3.48)	0.0068	
	3L+	37/ 86 (43.0)	13.73 (9.13, 13.73)	15/ 83 (18.1)	NE (12.94, NE)	2.53 (1.39, 4.62)	0.0017	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.2.S Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Investigations	Age (years)							0.4112
	<65	10/ 155 (6.5)	NE (14.88, NE)	1/ 137 (0.7)	NE (NE , NE)	7.03 (0.88, 55.97)	0.0321	
	>=65	2/ 88 (2.3)	NE (NE , NE)	1/ 101 (1.0)	NE (NE , NE)	2.17 (0.20, 24.05)	0.5159	
	Sex							
	Male	7/ 139 (5.0)		0/ 135 (0.0)				
	Female	5/ 104 (4.8)		2/ 103 (1.9)				
	Disease Status 2L							
	2L: progression of disease <= 2 years	5/ 63 (7.9)		0/ 61 (0.0)				
	2L: progression of disease > 2 years	3/ 94 (3.2)		1/ 94 (1.1)				
	Disease Status 3L+							
	3L+: < 6 months	2/ 23 (8.7)		1/ 22 (4.5)				
	3L+: >= 6 months	2/ 63 (3.2)		0/ 61 (0.0)				
	Region							0.9915
	US/Western Europe	0/ 58 (0.0)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	NE		
	Rest of world	12/ 185 (6.5)	NE (14.88, NE)	1/ 181 (0.6)	NE (NE , NE)	9.73 (1.25, 75.81)	0.0077	
	Number of prior anti-lymphoma therapies							
	2L	8/ 157 (5.1)		1/ 155 (0.6)				
	3L+	4/ 86 (4.7)		1/ 83 (1.2)				

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.2.S Time to first frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders	Age (years)							0.5606
	<65	3/ 155 (1.9)	NE (NE , NE)	5/ 137 (3.6)	NE (NE , NE)	0.50 (0.12, 2.08)	0.3286	
	>=65	2/ 88 (2.3)	NE (NE , NE)	8/ 101 (7.9)	NE (NE , NE)	0.25 (0.05, 1.20)	0.0625	
	Sex							0.2338
	Male	4/ 139 (2.9)	NE (NE , NE)	6/ 135 (4.4)	NE (NE , NE)	0.59 (0.17, 2.10)	0.4127	
	Female	1/ 104 (1.0)	NE (NE , NE)	7/ 103 (6.8)	NE (NE , NE)	0.13 (0.02, 1.06)	0.0247	
	Disease Status 2L							
	2L: progression of disease <= 2 years	0/ 63 (0.0)		5/ 61 (8.2)				
	2L: progression of disease > 2 years	2/ 94 (2.1)		4/ 94 (4.3)				
	Disease Status 3L+							
	3L+: < 6 months	2/ 23 (8.7)		1/ 22 (4.5)				
	3L+: >= 6 months	1/ 63 (1.6)		3/ 61 (4.9)				
	Region							0.1973
	US/Western Europe	1/ 58 (1.7)	NE (NE , NE)	7/ 57 (12.3)	NE (NE , NE)	0.12 (0.02, 1.01)	0.0201	
	Rest of world	4/ 185 (2.2)	NE (NE , NE)	6/ 181 (3.3)	NE (NE , NE)	0.60 (0.17, 2.14)	0.4293	
	Number of prior anti-lymphoma therapies							0.2559
	2L	2/ 157 (1.3)	NE (NE , NE)	9/ 155 (5.8)	NE (NE , NE)	0.20 (0.04, 0.94)	0.0234	
	3L+	3/ 86 (3.5)	NE (NE , NE)	4/ 83 (4.8)	NE (NE , NE)	0.67 (0.15, 2.98)	0.5918	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders	Number of subjects with events, n/N (%)	130/243 (53.5)	78/238 (32.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	1.84 (1.41, 2.37)	3.94 (1.94, 7.20)
	Median (95% CI)	7.62 (5.06, NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.82 (1.38, 2.41)	
	p-value	<.0001	
	Relative Risk (95% CI)	1.63 (1.31, 2.03)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.36 (1.63, 3.42)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.21 (0.12, 0.29)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n/N (%)	19/243 (7.8)	11/238 (4.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	17.48 (NE , NE)	NE (NE , NE)
	Median (95% CI)	17.48 (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	17.48 (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.52 (0.72, 3.23)	
	p-value	0.2683	
	Relative Risk (95% CI)	1.69 (0.82, 3.48)	
	p-value	0.1528	
	Odds Ratio (95% CI)	1.75 (0.81, 3.76)	
	p-value	0.1516	
	Risk Difference (95% CI)	0.03 (-0.01, 0.07)	
	p-value	0.1453	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Febrile neutropenia	Number of subjects with events, n/N (%)	15/243 (6.2)	6/238 (2.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.29 (0.89, 5.91)	
	p-value	0.0780	
	Relative Risk (95% CI)	2.45 (0.97, 6.20)	
	p-value	0.0591	
	Odds Ratio (95% CI)	2.54 (0.97, 6.67)	
	p-value	0.0577	
	Risk Difference (95% CI)	0.04 (0.00, 0.07)	
	p-value	0.0482	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Lymphopenia	Number of subjects with events, n/N (%)	15/243 (6.2)	4/238 (1.7)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	3.59 (1.19, 10.84)	
	p-value	0.0149	
	Relative Risk (95% CI)	3.67 (1.24, 10.91)	
	p-value	0.0191	
	Odds Ratio (95% CI)	3.85 (1.26, 11.77)	
	p-value	0.0181	
	Risk Difference (95% CI)	0.04 (0.01, 0.08)	
	p-value	0.0104	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Number of subjects with events, n/N (%)	112/243 (46.1)	61/238 (25.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	2.56 (1.94, 2.86)	7.43 (4.67, NE)
	Median (95% CI)	NE (7.82, NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.93 (1.42, 2.64)	
	p-value	<.0001	
	Relative Risk (95% CI)	1.80 (1.39, 2.32)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.48 (1.69, 3.65)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.20 (0.12, 0.29)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia	Number of subjects with events, n/N (%)	16/243 (6.6)	13/238 (5.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.15 (0.55, 2.40)	
	p-value	0.7054	
	Relative Risk (95% CI)	1.21 (0.59, 2.45)	
	p-value	0.6058	
	Odds Ratio (95% CI)	1.22 (0.57, 2.59)	
	p-value	0.6057	
	Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
	p-value	0.6048	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Gastrointestinal disorders	Number of subjects with events, n/N (%)	17/243 (7.0)	12/238 (5.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (14.32, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.20 (0.57, 2.54)	
	p-value	0.6350	
	Relative Risk (95% CI)	1.39 (0.68, 2.84)	
	p-value	0.3707	
	Odds Ratio (95% CI)	1.42 (0.66, 3.03)	
	p-value	0.3701	
	Risk Difference (95% CI)	0.02 (-0.02, 0.06)	
	p-value	0.3669	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n/N (%)	10/243 (4.1)	7/238 (2.9)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (14.32, NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.11 (0.41, 2.99)	
	p-value	0.8354	
	Relative Risk (95% CI)	1.40 (0.54, 3.61)	
	p-value	0.4880	
	Odds Ratio (95% CI)	1.42 (0.53, 3.78)	
	p-value	0.4876	
	Risk Difference (95% CI)	0.01 (-0.02, 0.04)	
	p-value	0.4847	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: General disorders and administration site conditions	Number of subjects with events, n/N (%)	16/243 (6.6)	11/238 (4.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.31 (0.61, 2.83)	
	p-value	0.4904	
	Relative Risk (95% CI)	1.42 (0.68, 3.01)	
	p-value	0.3528	
	Odds Ratio (95% CI)	1.45 (0.66, 3.20)	
	p-value	0.3522	
	Risk Difference (95% CI)	0.02 (-0.02, 0.06)	
	p-value	0.3486	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations	Number of subjects with events, n/N (%)	81/243 (33.3)	37/238 (15.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	6.77 (3.52, 9.99)	12.94 (12.94, NE)
	Median (95% CI)	NE (13.73, NE)	NE (12.94, NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.10 (1.42, 3.10)	
	p-value	0.0001	
	Relative Risk (95% CI)	2.14 (1.52, 3.03)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.72 (1.75, 4.22)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.18 (0.10, 0.25)	
	p-value	<.0001	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n/N (%)	28/243 (11.5)	12/238 (5.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.07 (1.05, 4.07)	
	p-value	0.0317	
	Relative Risk (95% CI)	2.29 (1.19, 4.39)	
	p-value	0.0130	
	Odds Ratio (95% CI)	2.45 (1.22, 4.95)	
	p-value	0.0122	
	Risk Difference (95% CI)	0.06 (0.02, 0.11)	
	p-value	0.0093	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations	Number of subjects with events, n/N (%)	91/243 (37.4)	55/238 (23.1)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	2.10 (1.61, 3.98)	9.49 (5.59, NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.72 (1.23, 2.40)	
	p-value	0.0013	
	Relative Risk (95% CI)	1.62 (1.22, 2.15)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.99 (1.34, 2.97)	
	p-value	0.0007	
	Risk Difference (95% CI)	0.14 (0.06, 0.22)	
	p-value	0.0005	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Alanine aminotransferase increased	Number of subjects with events, n/N (%)	15/243 (6.2)	2/238 (0.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	7.21 (1.65, 31.55)	
	p-value	0.0021	
	Relative Risk (95% CI)	7.35 (1.70, 31.77)	
	p-value	0.0076	
	Odds Ratio (95% CI)	7.76 (1.76, 34.33)	
	p-value	0.0069	
	Risk Difference (95% CI)	0.05 (0.02, 0.09)	
	p-value	0.0013	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Lymphocyte count decreased	Number of subjects with events, n/N (%)	16/243 (6.6)	6/238 (2.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.53 (0.99, 6.48)	
	p-value	0.0441	
	Relative Risk (95% CI)	2.61 (1.04, 6.56)	
	p-value	0.0411	
	Odds Ratio (95% CI)	2.73 (1.05, 7.09)	
	p-value	0.0398	
	Risk Difference (95% CI)	0.04 (0.00, 0.08)	
	p-value	0.0314	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: Neutrophil count decreased	Number of subjects with events, n/N (%)	60/243 (24.7)	40/238 (16.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	9.40 (4.04, NE)	NE (9.40, NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.47 (0.98, 2.19)	
	p-value	0.0591	
	Relative Risk (95% CI)	1.47 (1.03, 2.10)	
	p-value	0.0352	
	Odds Ratio (95% CI)	1.62 (1.04, 2.54)	
	p-value	0.0340	
	Risk Difference (95% CI)	0.08 (0.01, 0.15)	
	p-value	0.0321	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Investigations, PT: White blood cell count decreased	Number of subjects with events, n/N (%)	11/243 (4.5)	13/238 (5.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.72 (0.32, 1.62)	
	p-value	0.4277	
	Relative Risk (95% CI)	0.83 (0.38, 1.81)	
	p-value	0.6381	
	Odds Ratio (95% CI)	0.82 (0.36, 1.87)	
	p-value	0.6380	
	Risk Difference (95% CI)	-0.01 (-0.05, 0.03)	
	p-value	0.6378	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Metabolism and nutrition disorders	Number of subjects with events, n/N (%)	30/243 (12.3)	10/238 (4.2)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.92 (1.43, 5.98)	
	p-value	0.0021	
	Relative Risk (95% CI)	2.94 (1.47, 5.88)	
	p-value	0.0023	
	Odds Ratio (95% CI)	3.21 (1.53, 6.73)	
	p-value	0.0020	
	Risk Difference (95% CI)	0.08 (0.03, 0.13)	
	p-value	0.0010	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Number of subjects with events, n/N (%)	16/243 (6.6)	6/238 (2.5)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.50 (0.98, 6.40)	
	p-value	0.0473	
	Relative Risk (95% CI)	2.61 (1.04, 6.56)	
	p-value	0.0411	
	Odds Ratio (95% CI)	2.73 (1.05, 7.09)	
	p-value	0.0398	
	Risk Difference (95% CI)	0.04 (0.00, 0.08)	
	p-value	0.0314	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n/N (%)	7/243 (2.9)	12/238 (5.0)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	0.51 (0.20, 1.31)	
	p-value	0.1545	
	Relative Risk (95% CI)	0.57 (0.23, 1.43)	
	p-value	0.2304	
	Odds Ratio (95% CI)	0.56 (0.22, 1.44)	
	p-value	0.2295	
	Risk Difference (95% CI)	-0.02 (-0.06, 0.01)	
	p-value	0.2243	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n/N (%)	29/243 (11.9)	18/238 (7.6)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	1.49 (0.83, 2.70)	
	p-value	0.1794	
	Relative Risk (95% CI)	1.58 (0.90, 2.76)	
	p-value	0.1106	
	Odds Ratio (95% CI)	1.66 (0.89, 3.07)	
	p-value	0.1093	
	Risk Difference (95% CI)	0.04 (-0.01, 0.10)	
	p-value	0.1048	

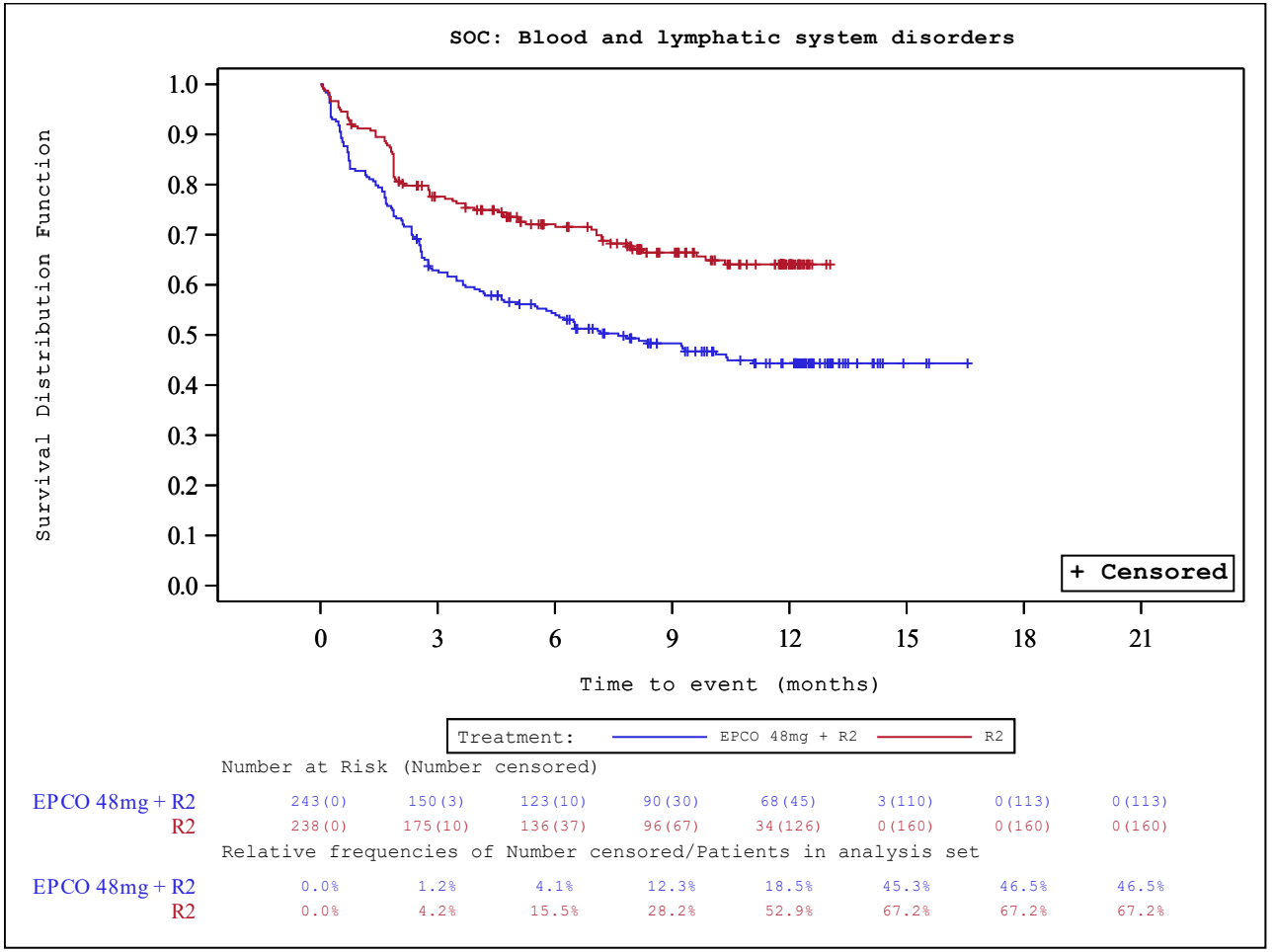
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.5.3 Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)

SOC / PT		EPCO 48mg + R2	R2
SOC: Skin and subcutaneous tissue disorders, PT: Rash	Number of subjects with events, n/N (%)	19/243 (7.8)	9/238 (3.8)
	Kaplan-Meier estimates of Time-to-event (months)		
	25%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Median (95% CI)	NE (NE , NE)	NE (NE , NE)
	75%-ile (95% CI)	NE (NE , NE)	NE (NE , NE)
	Analysis EPCO 48mg + R2 vs. R2		
	Hazard Ratio (95% CI)	2.00 (0.90, 4.42)	
	p-value	0.0810	
	Relative Risk (95% CI)	2.07 (0.95, 4.48)	
	p-value	0.0654	
	Odds Ratio (95% CI)	2.16 (0.96, 4.87)	
	p-value	0.0640	
	Risk Difference (95% CI)	0.04 (-0.00, 0.08)	
	p-value	0.0569	

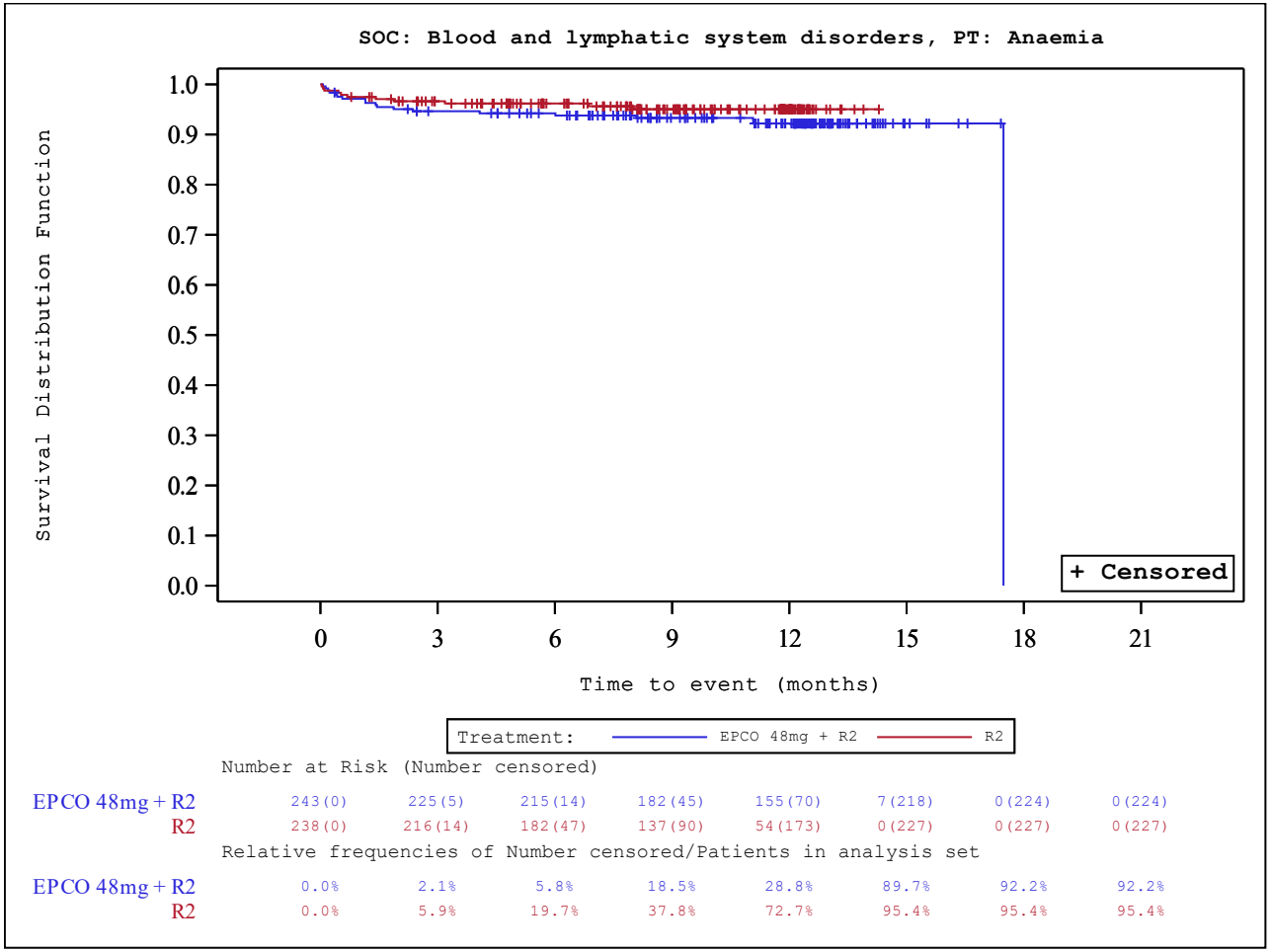
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



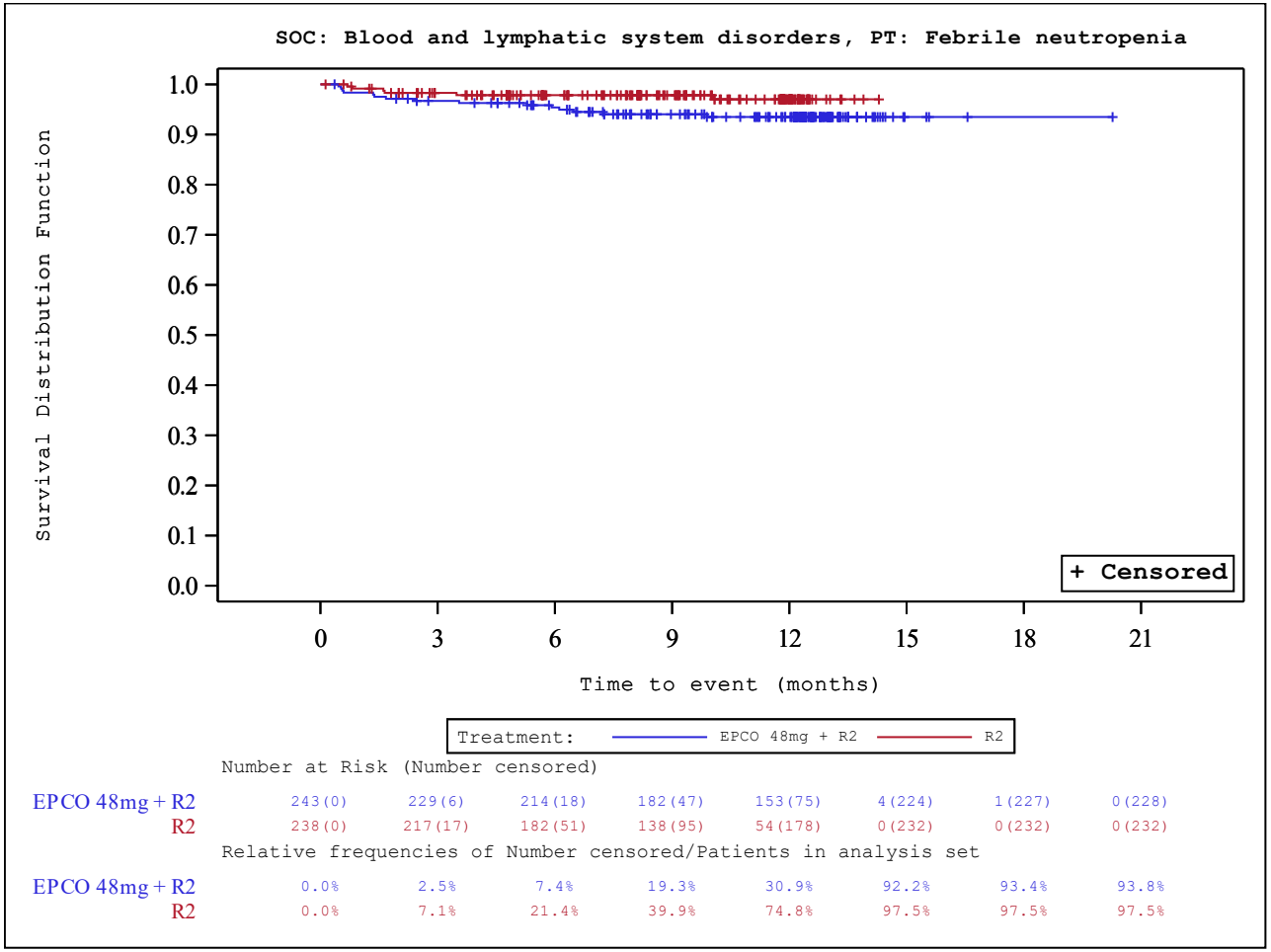
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



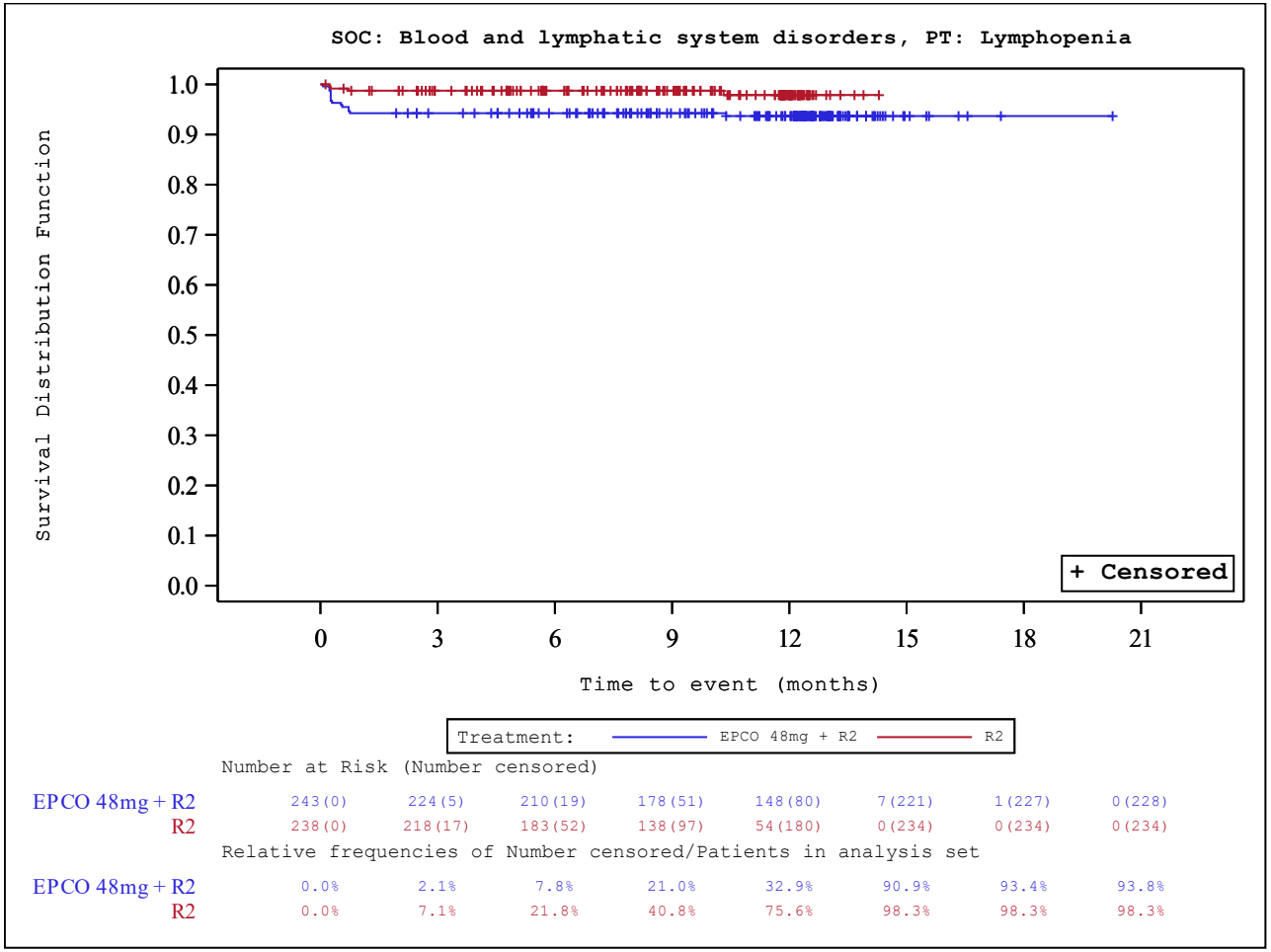
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



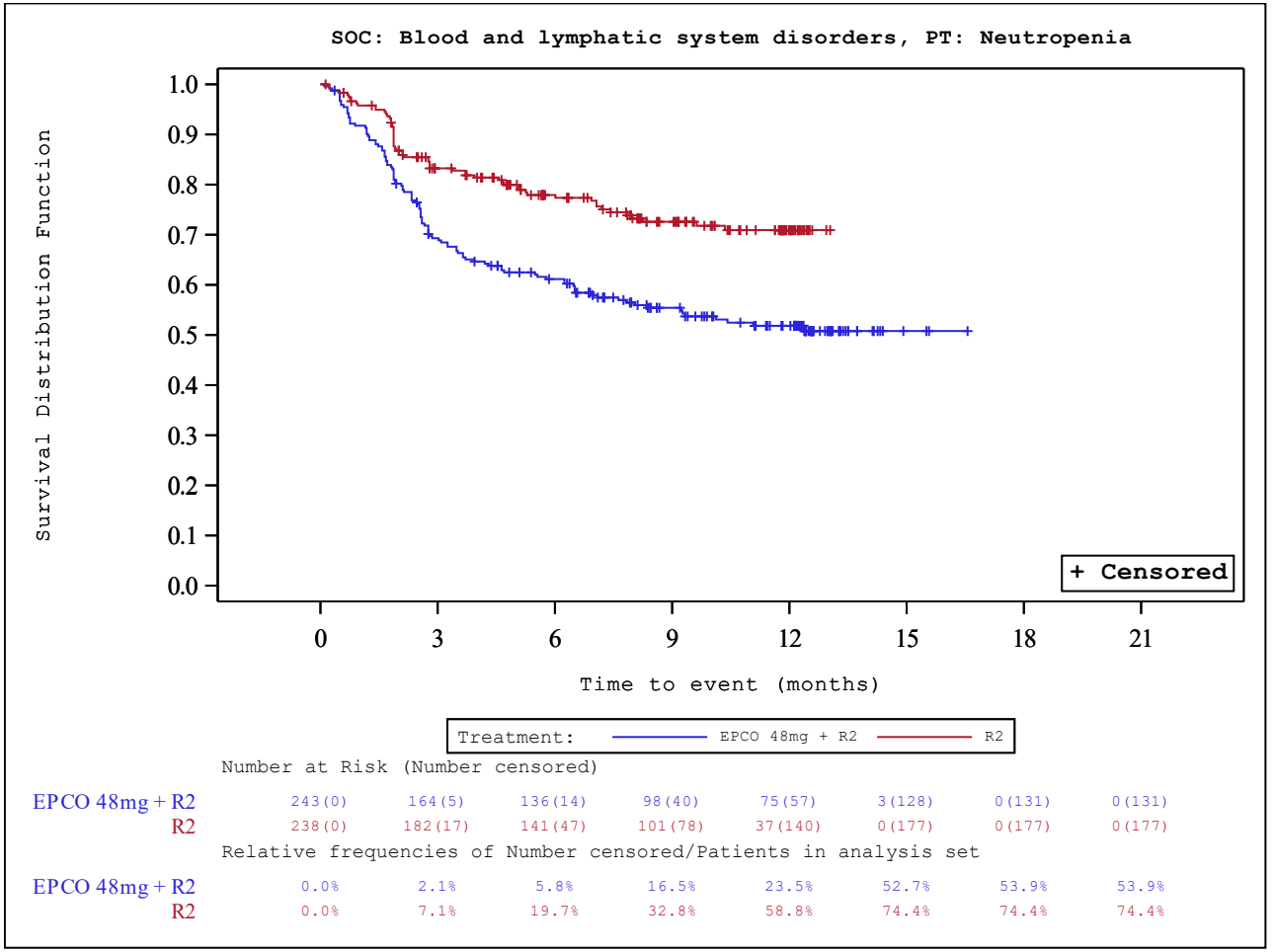
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



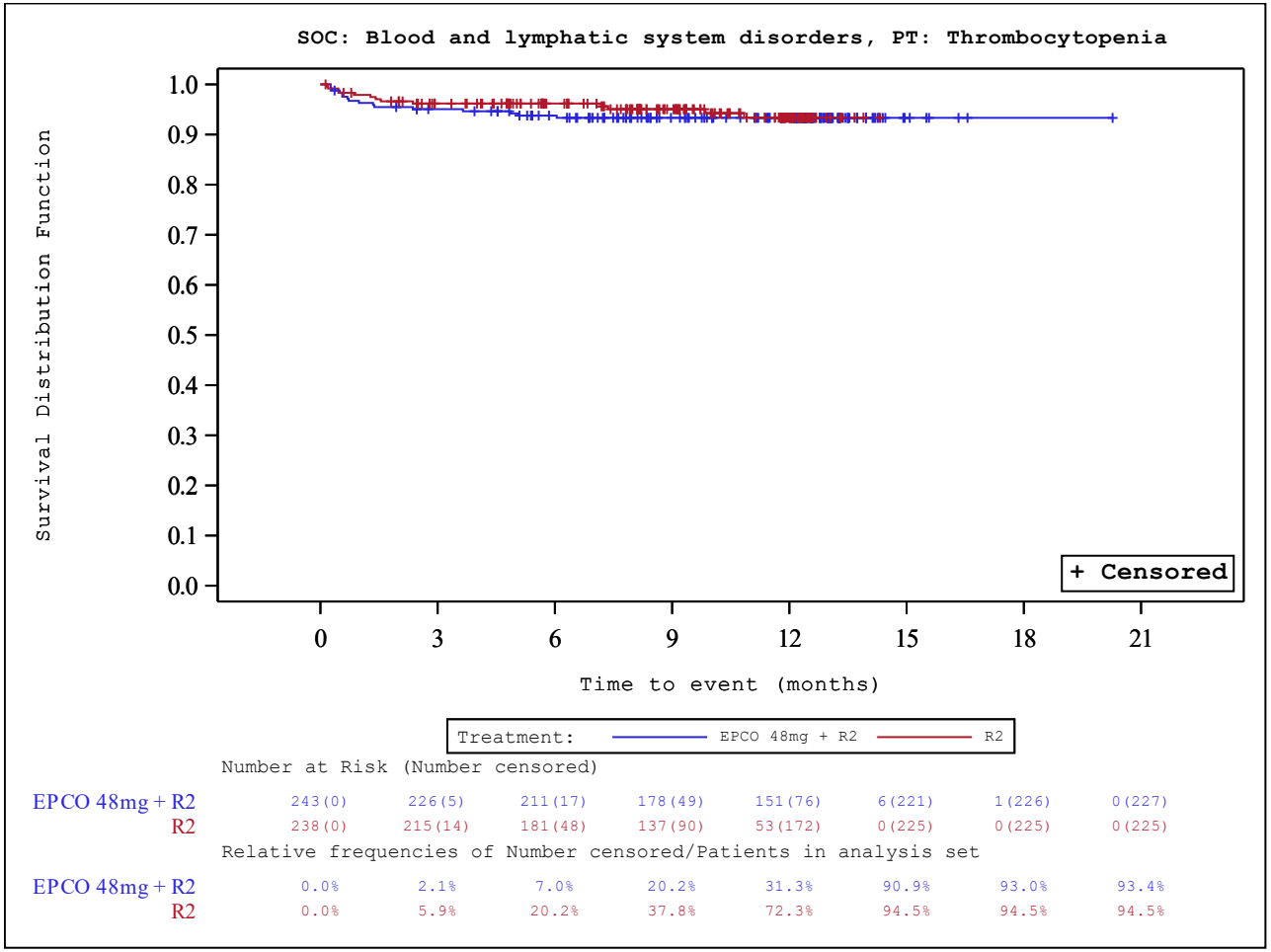
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



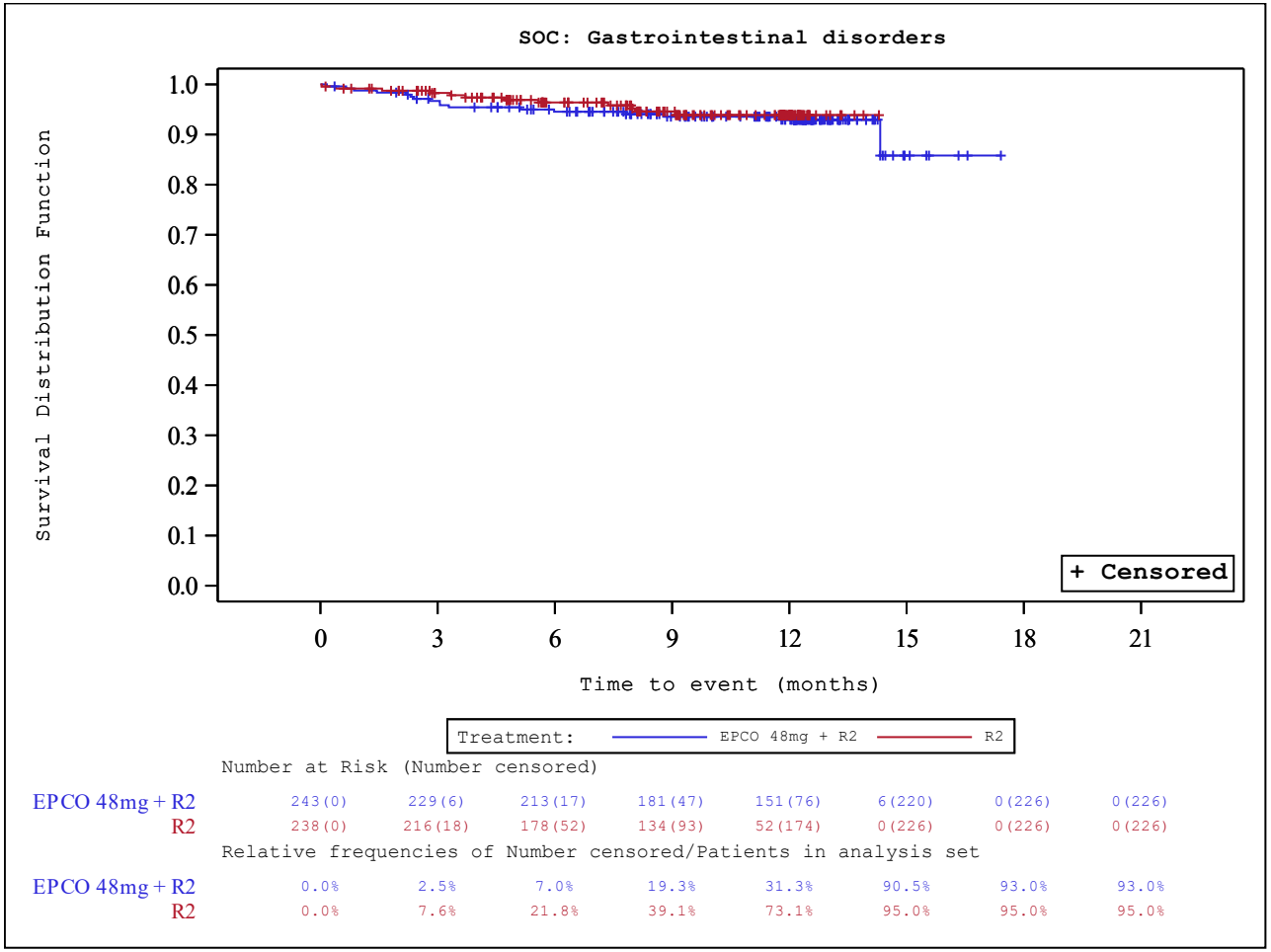
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



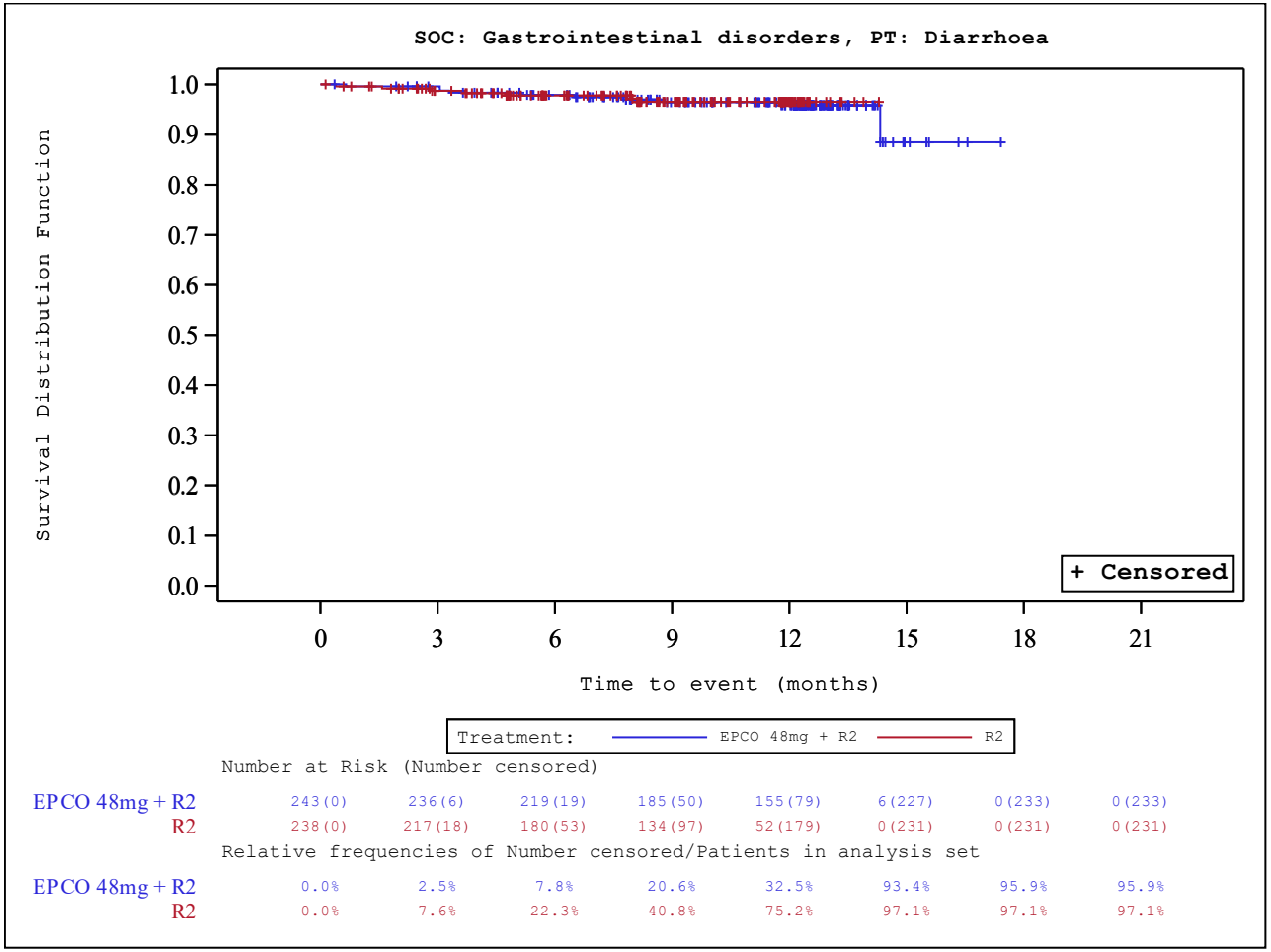
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



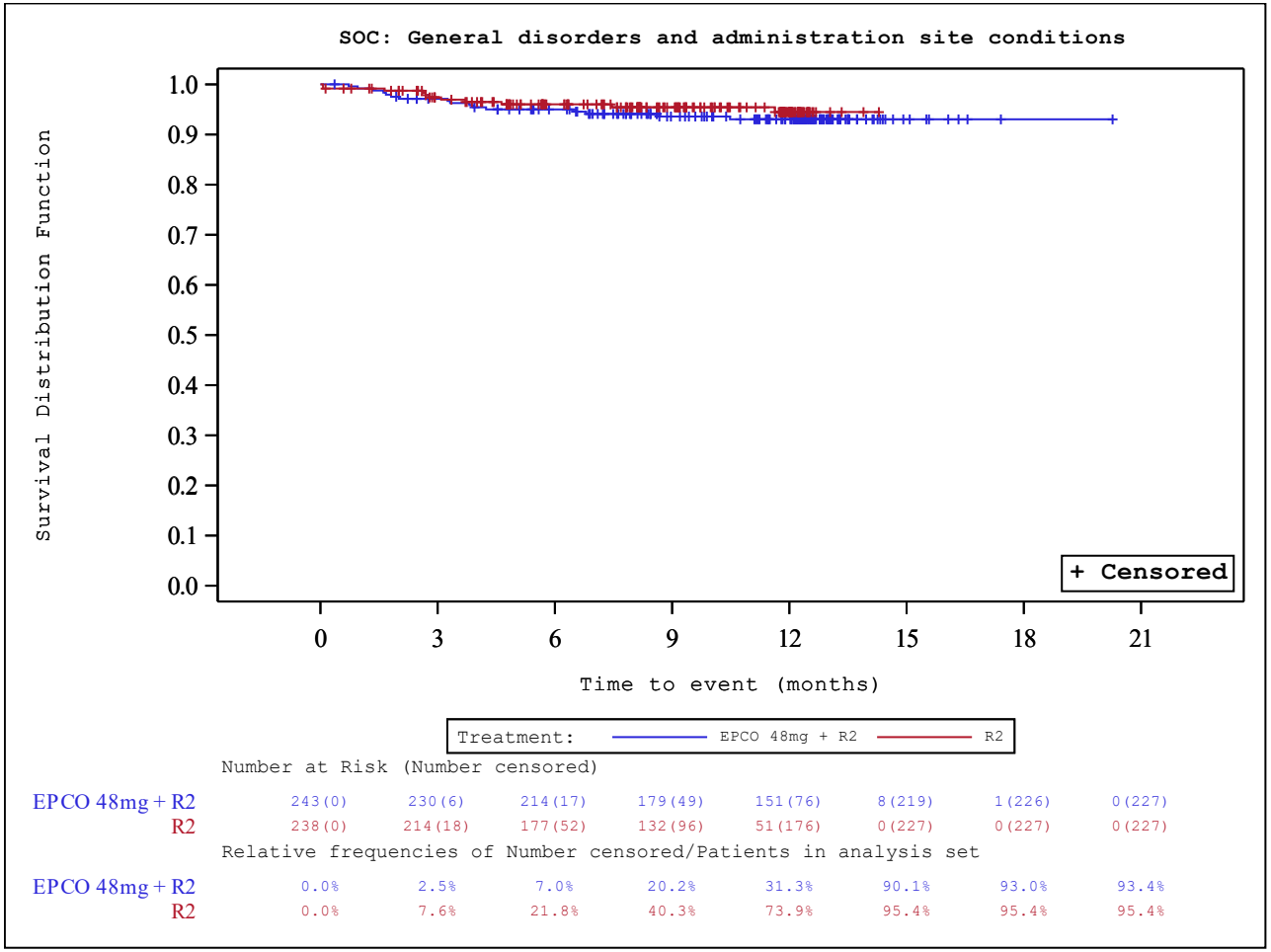
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



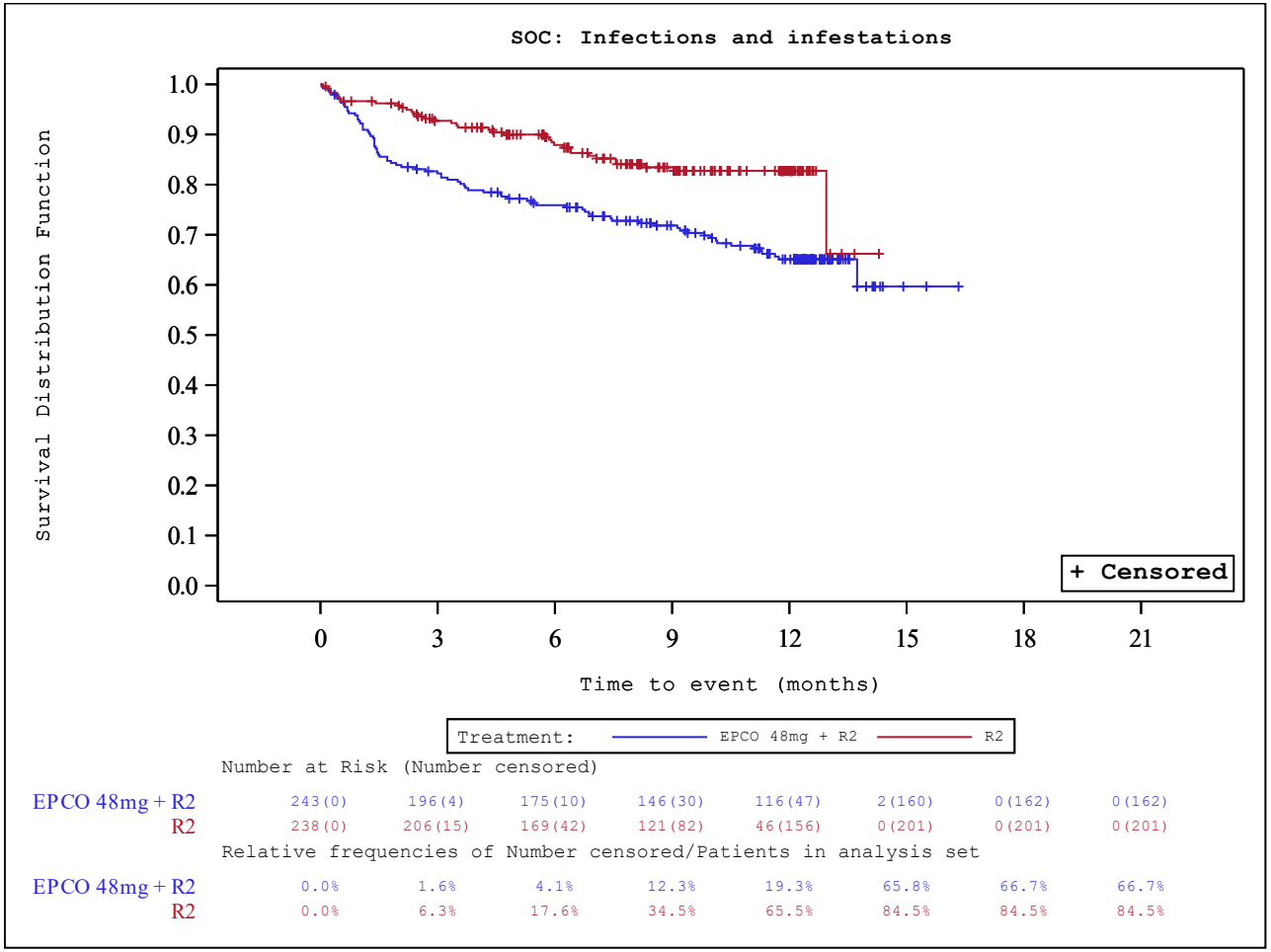
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



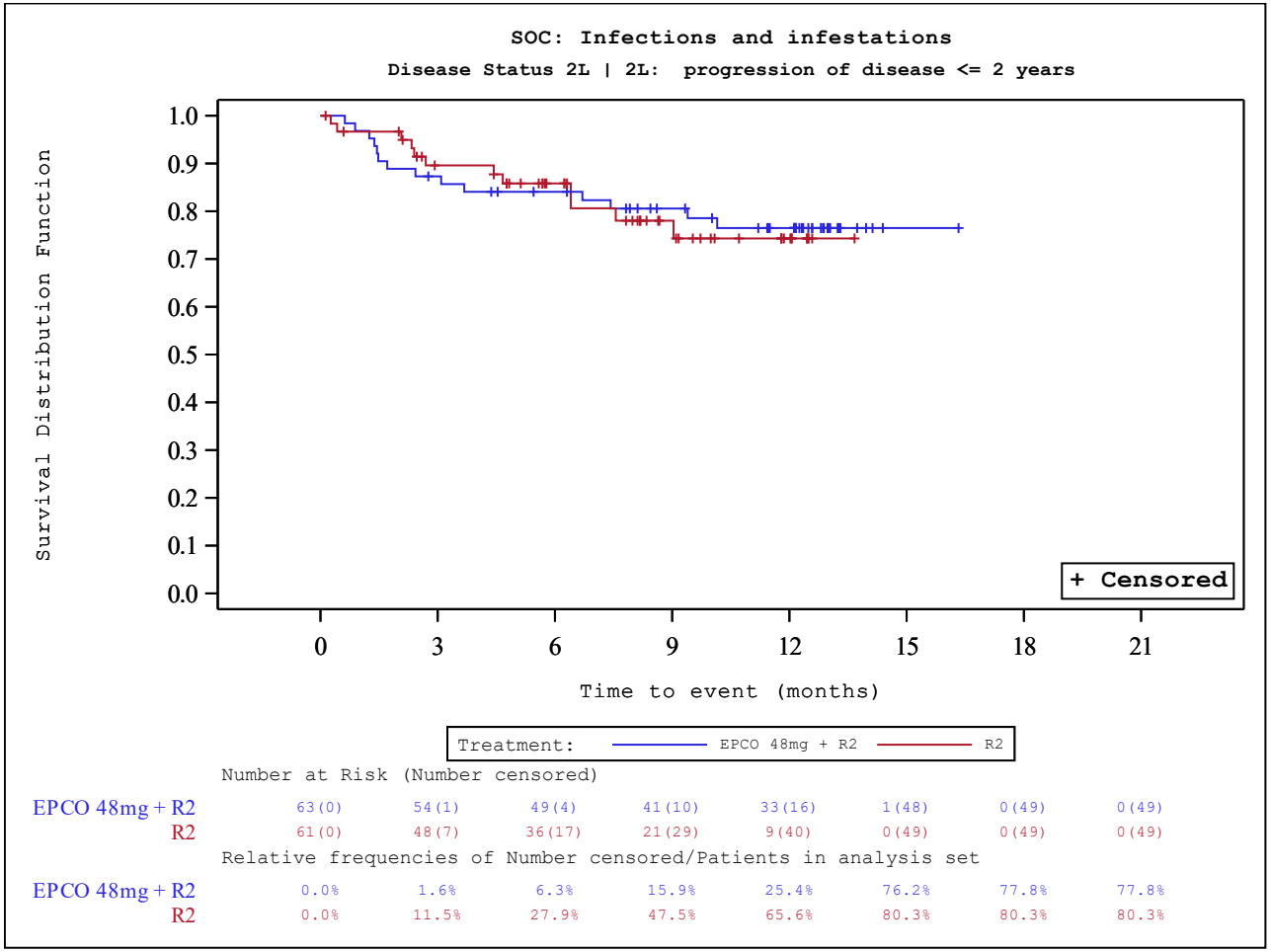
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



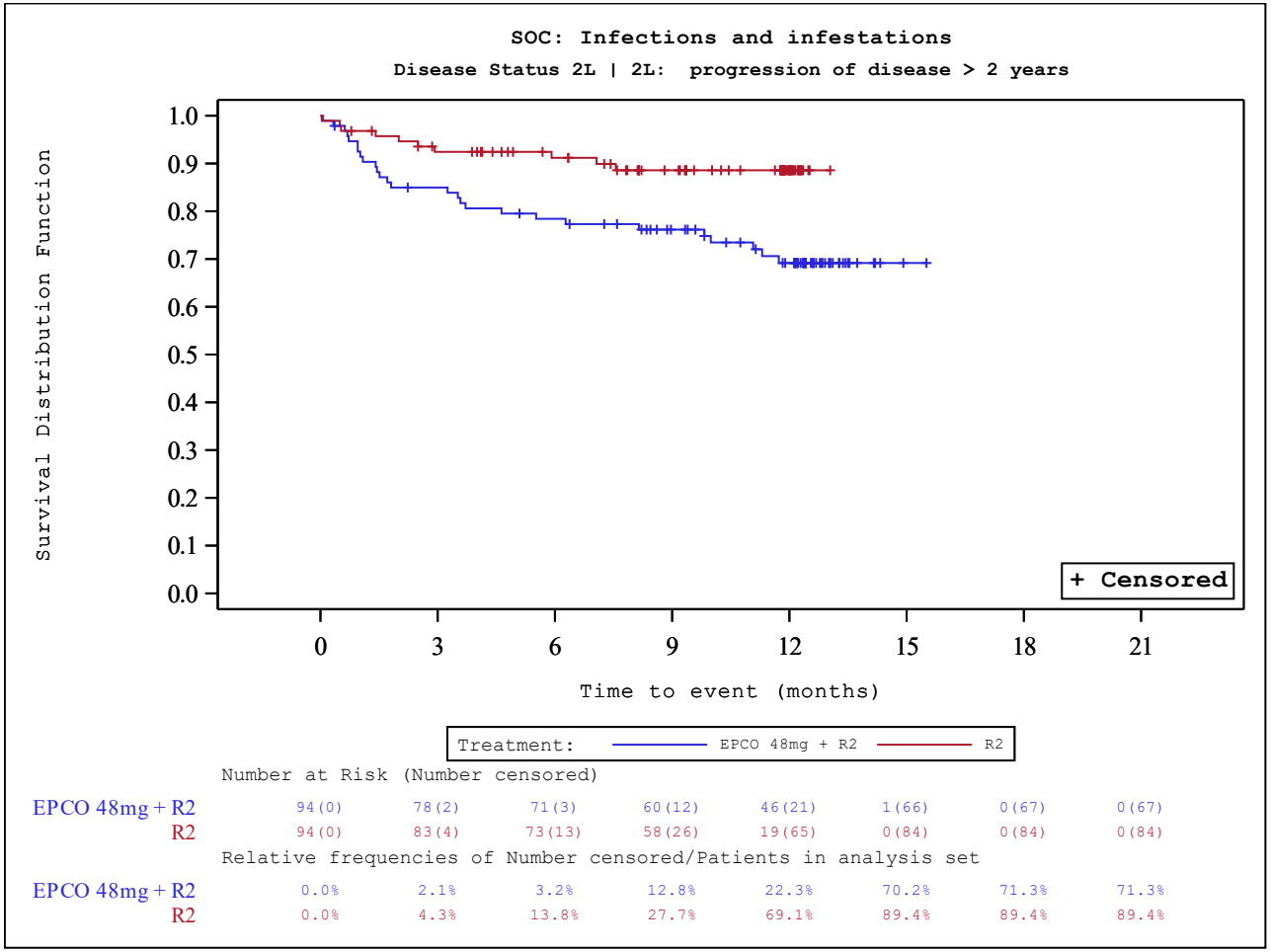
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



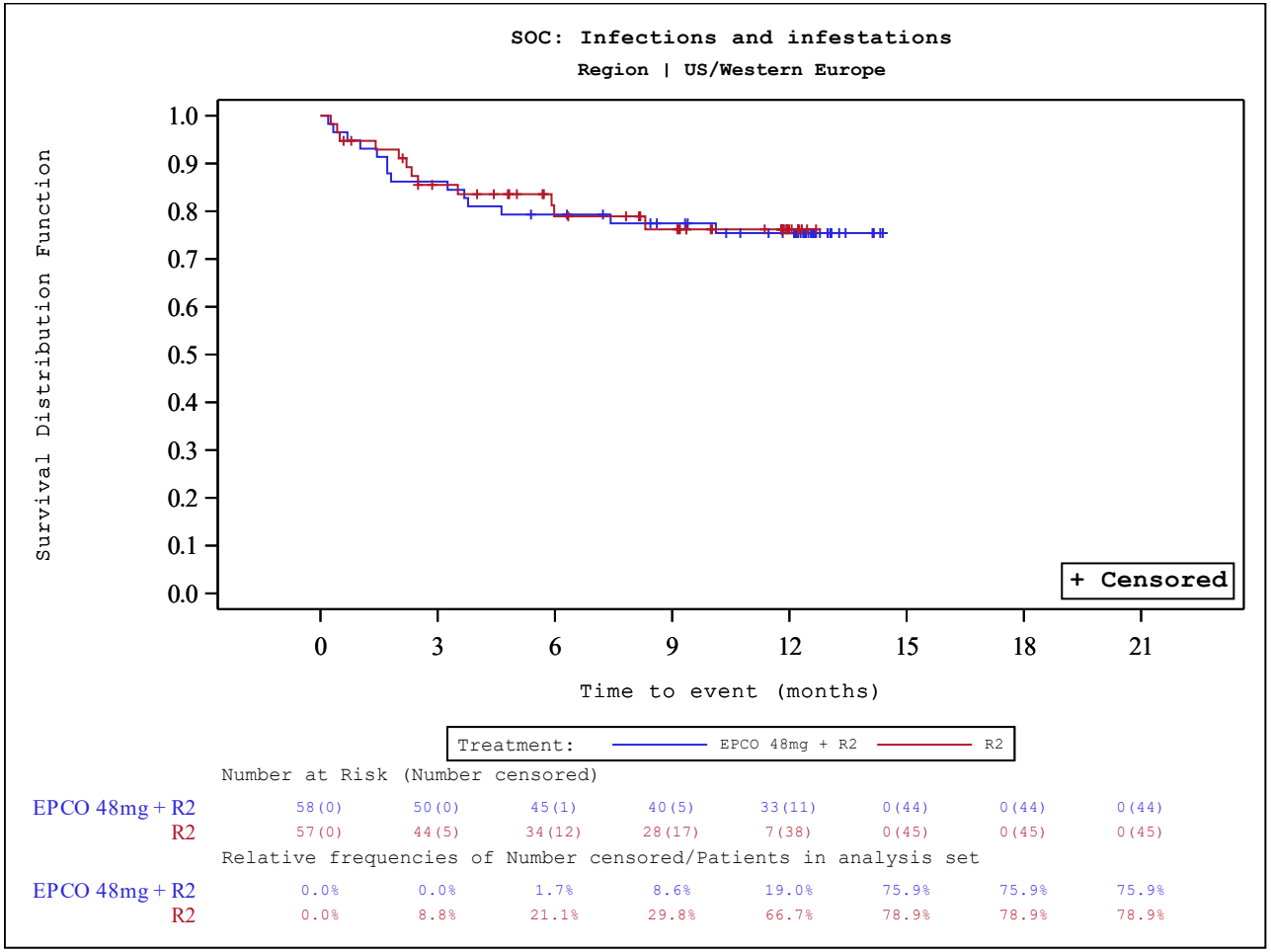
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



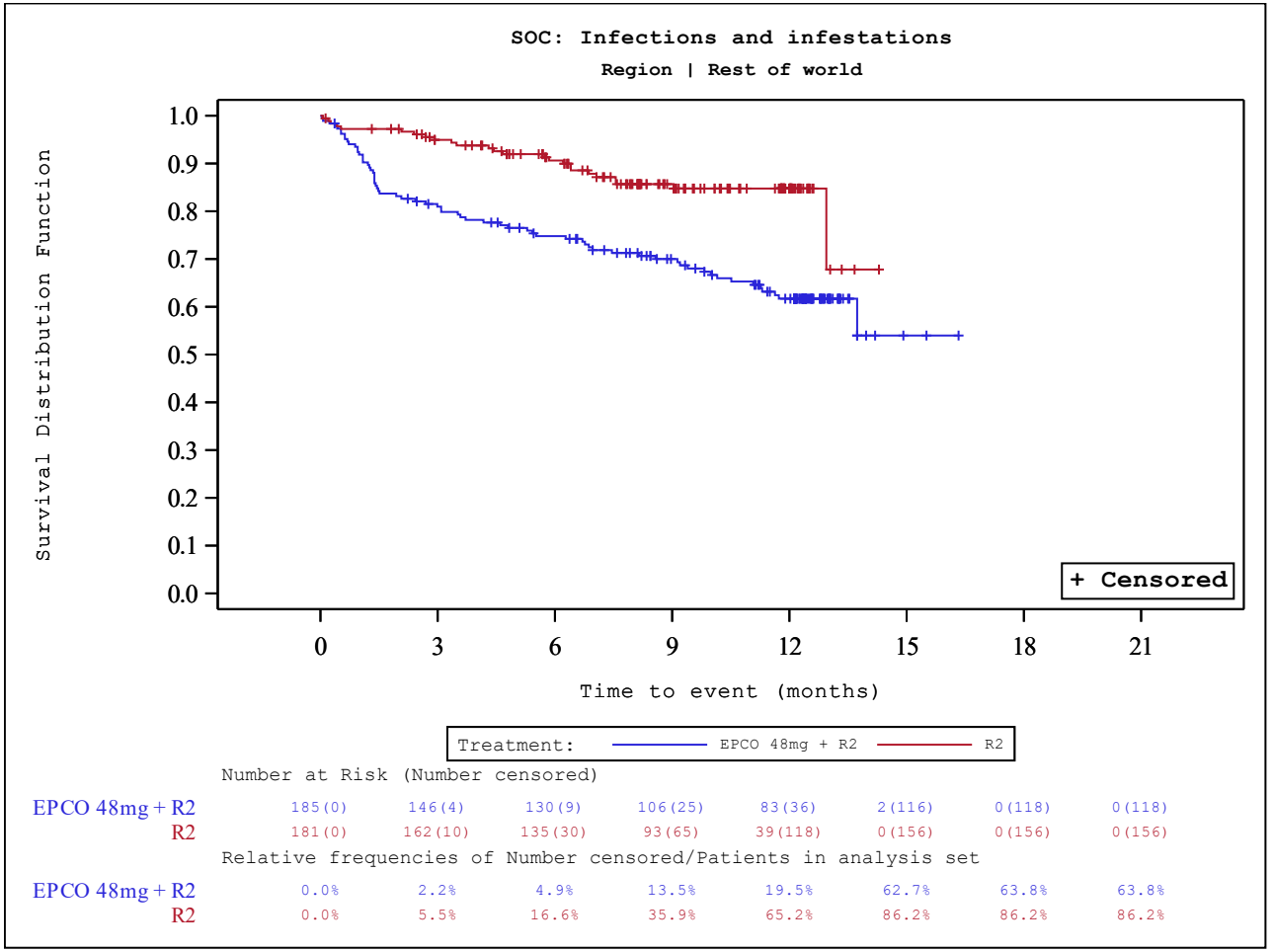
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



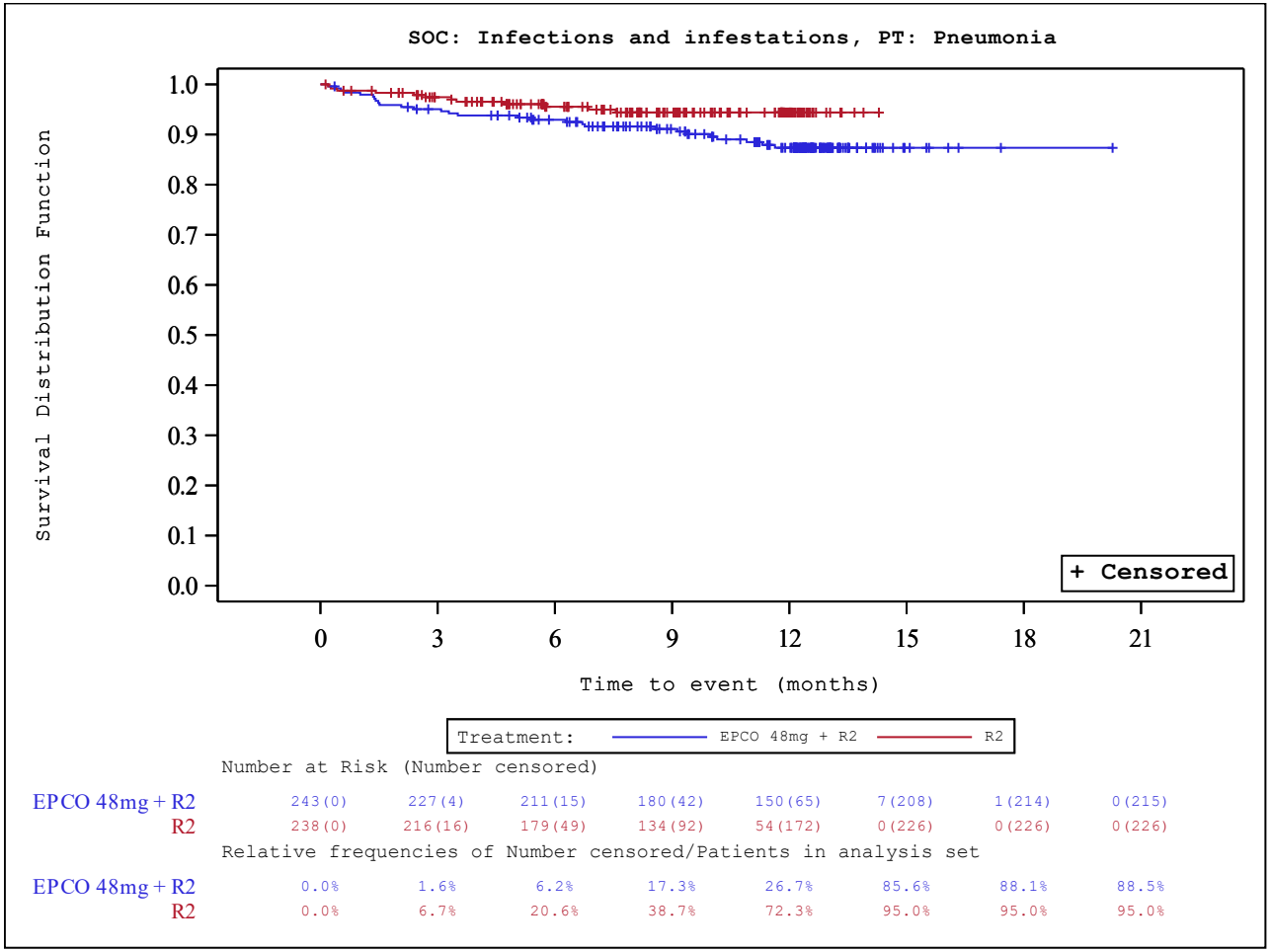
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



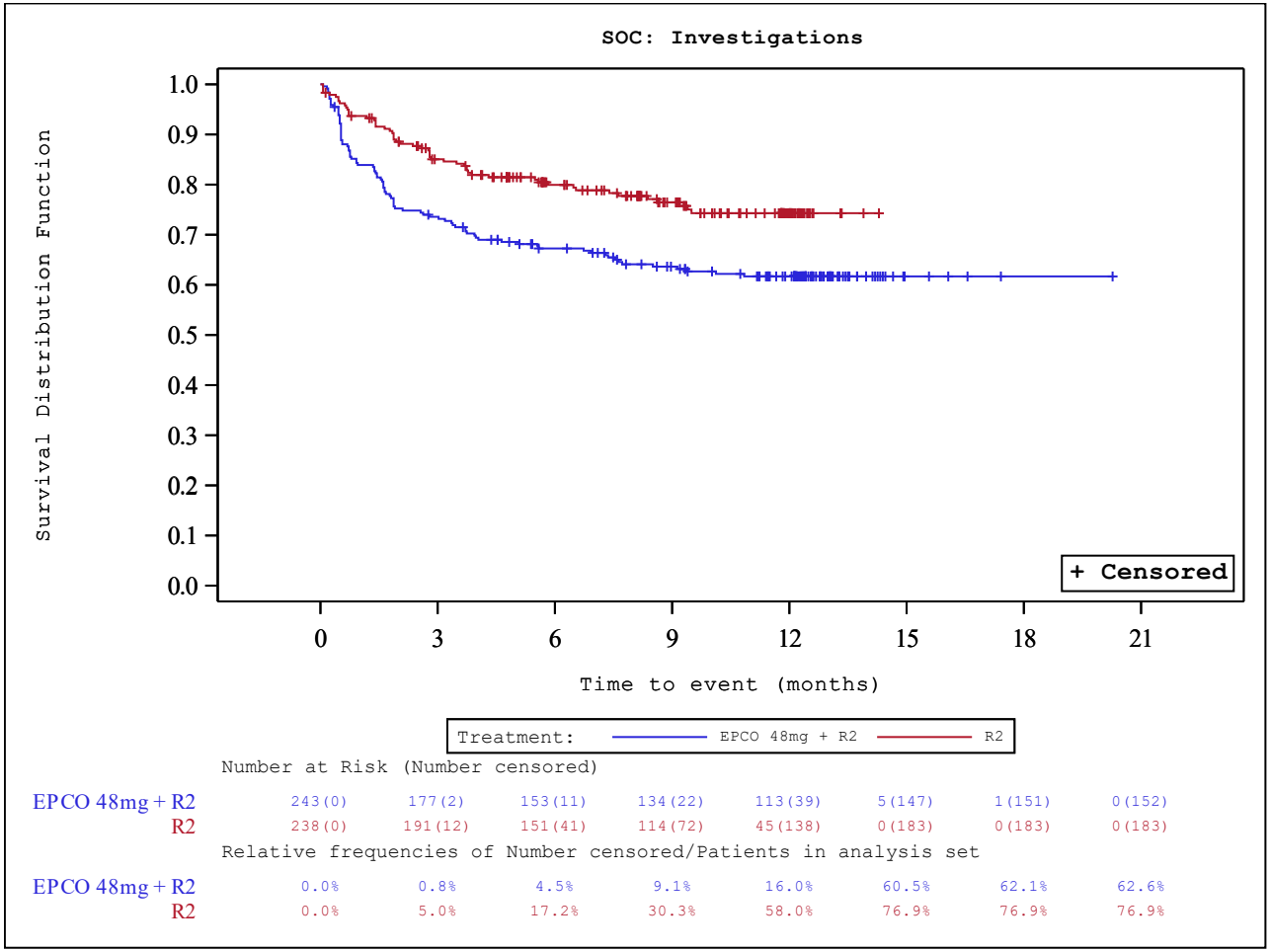
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



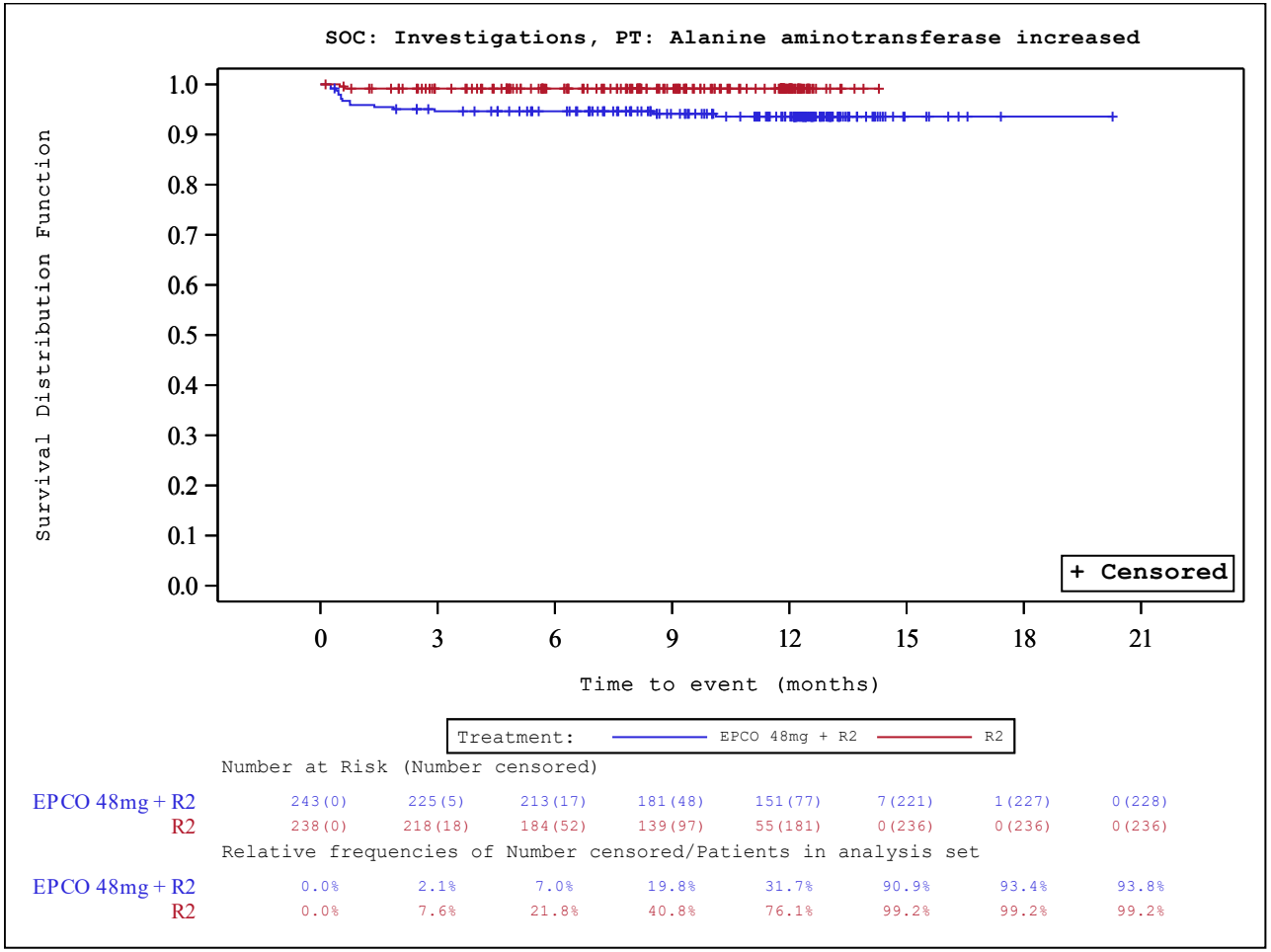
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



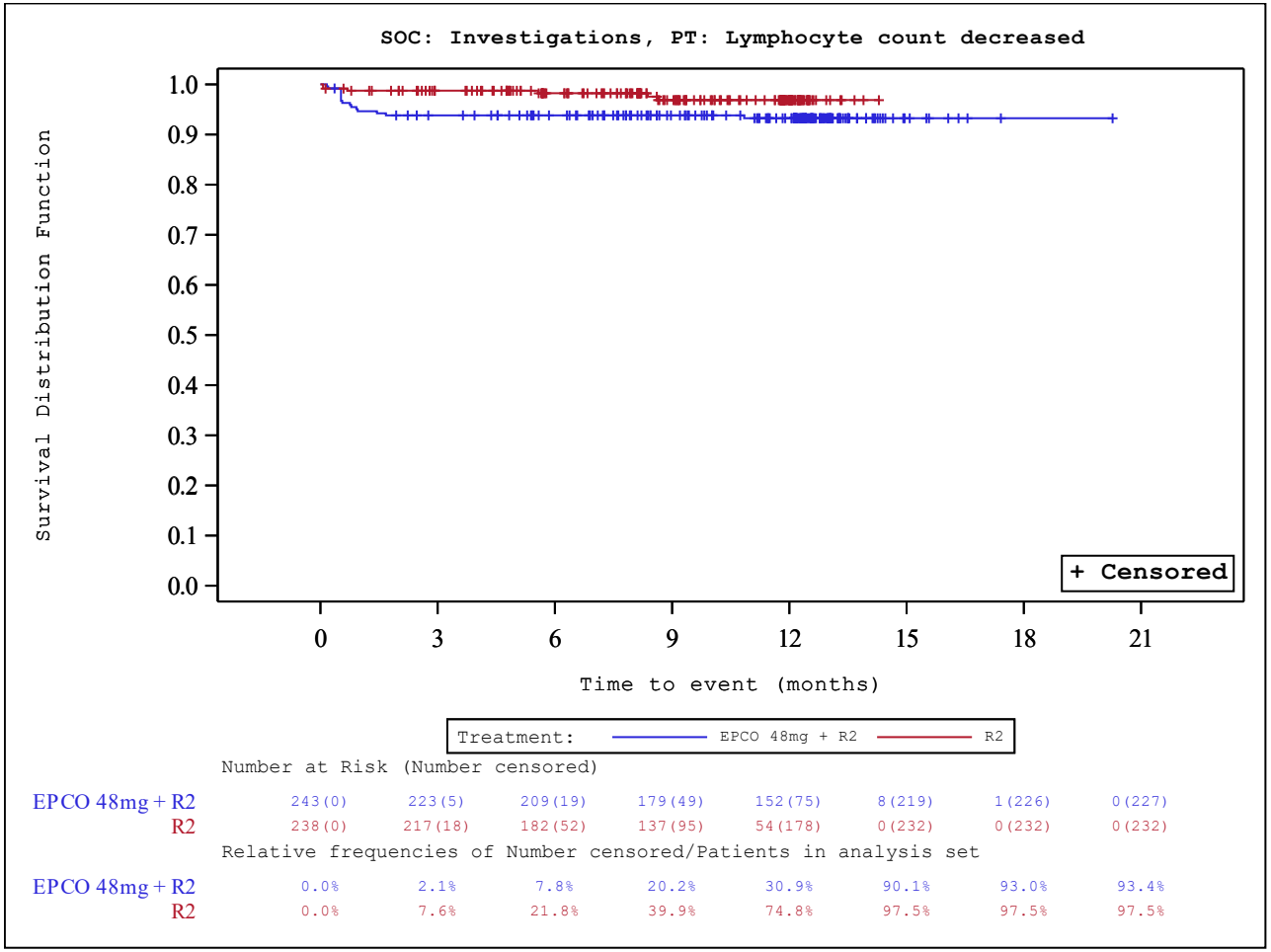
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



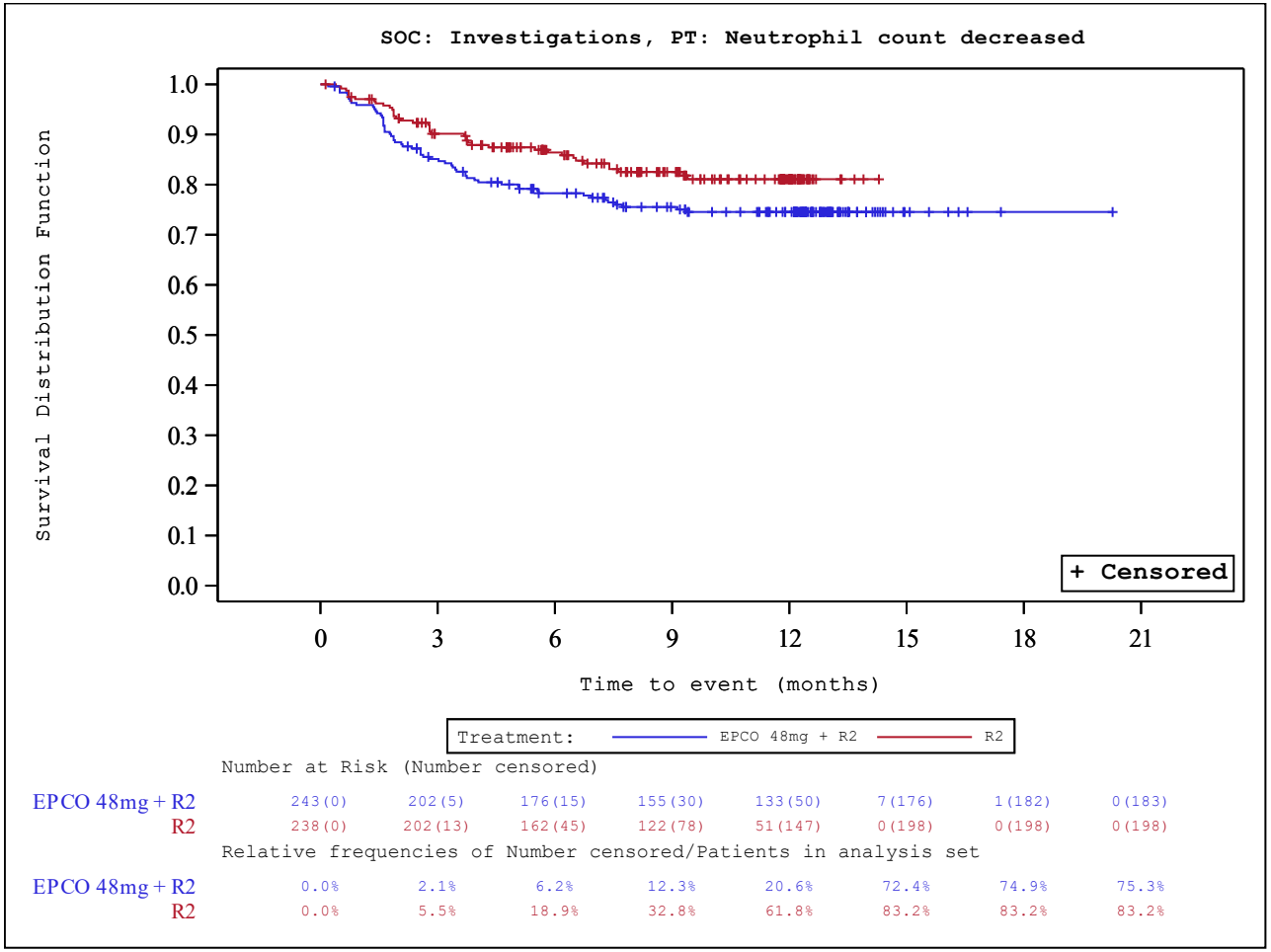
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



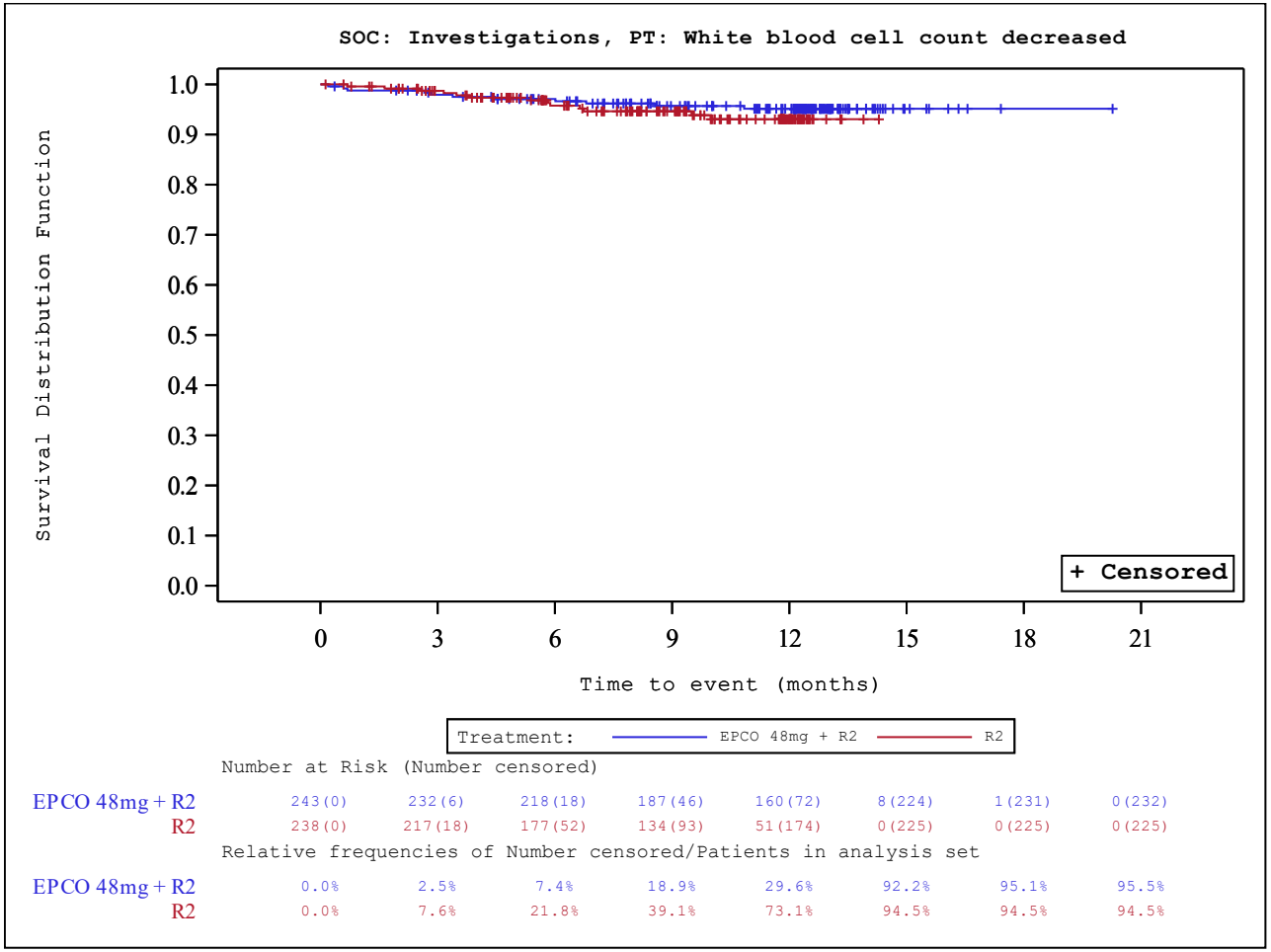
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



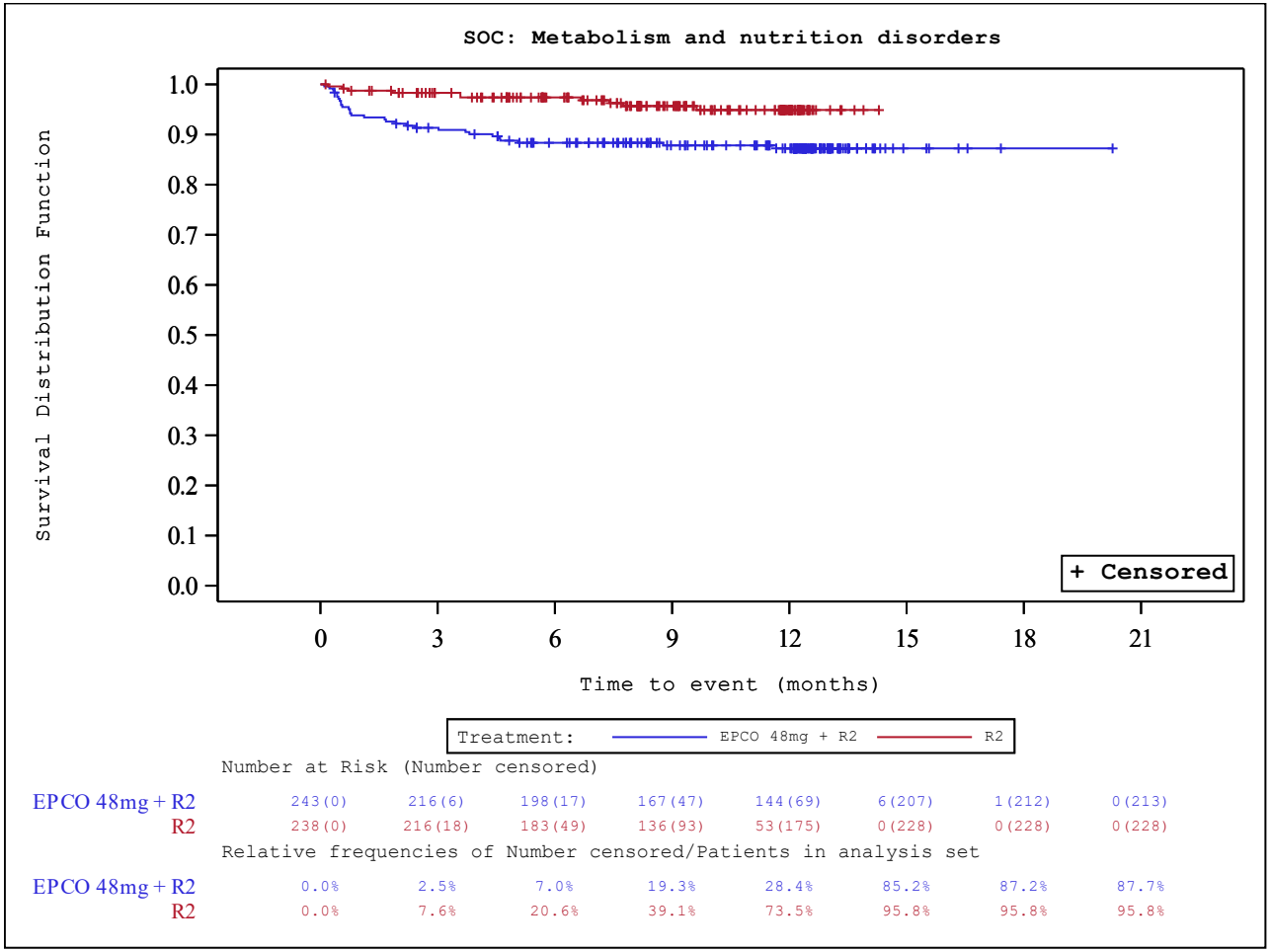
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



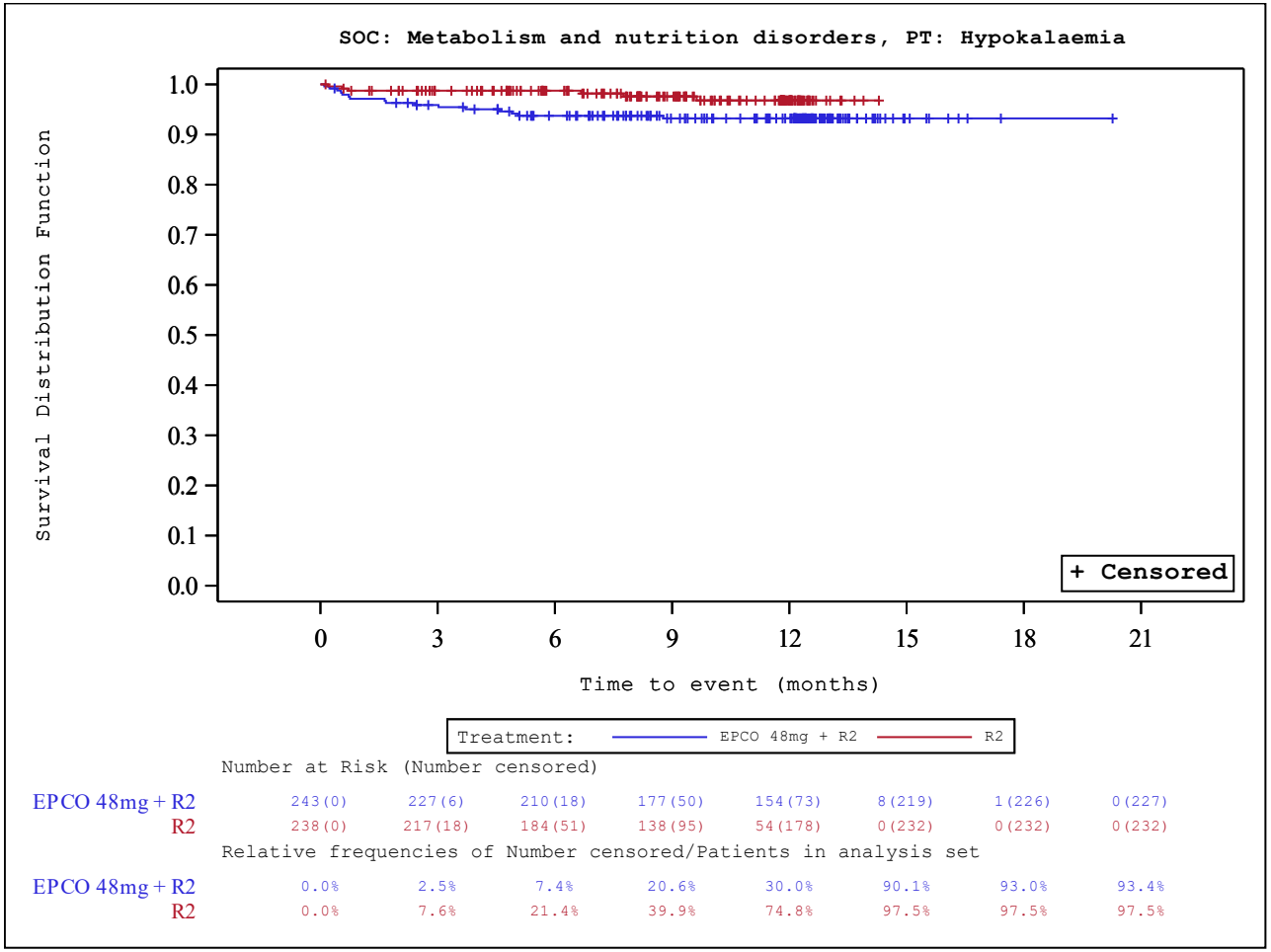
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



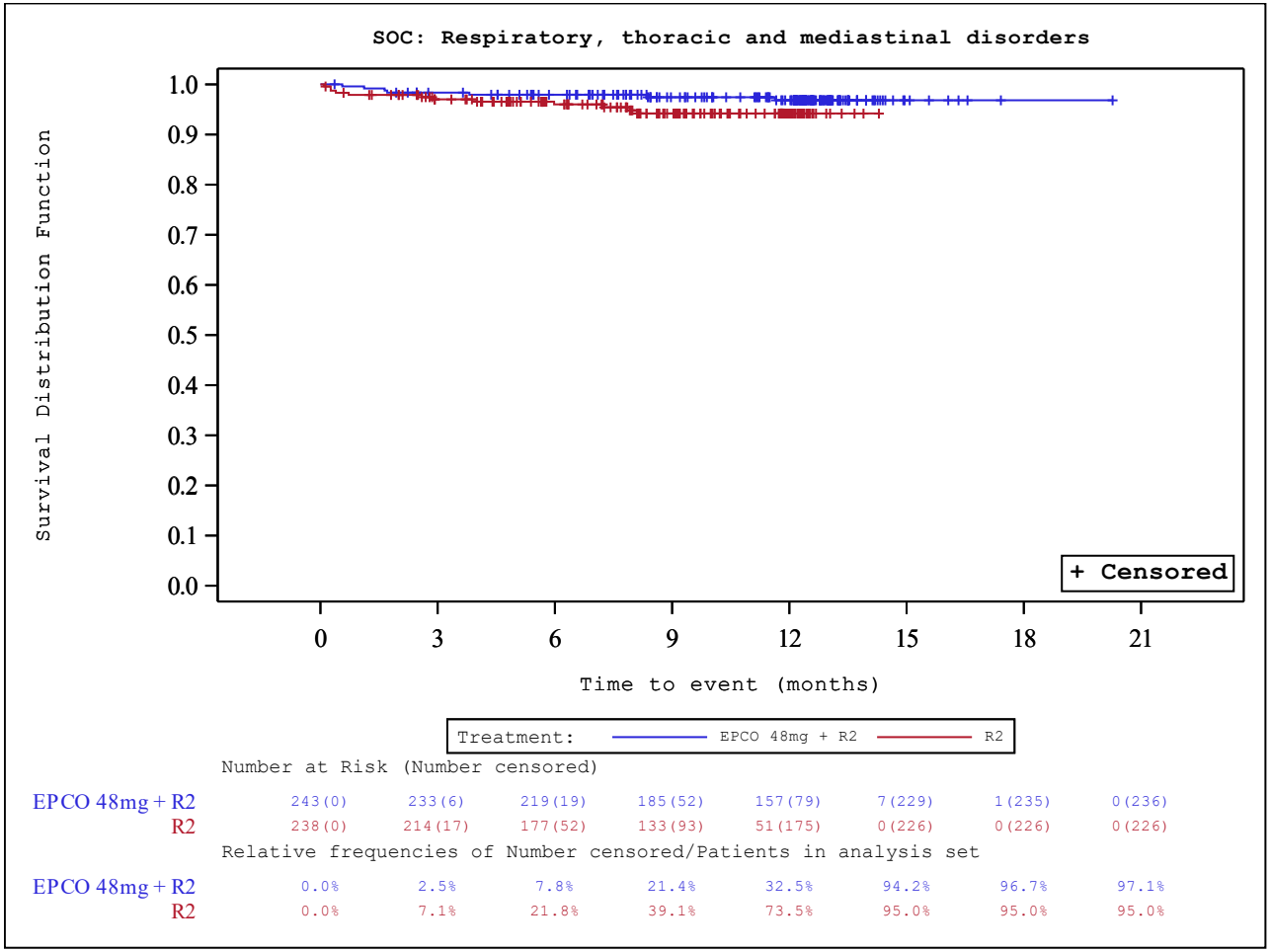
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



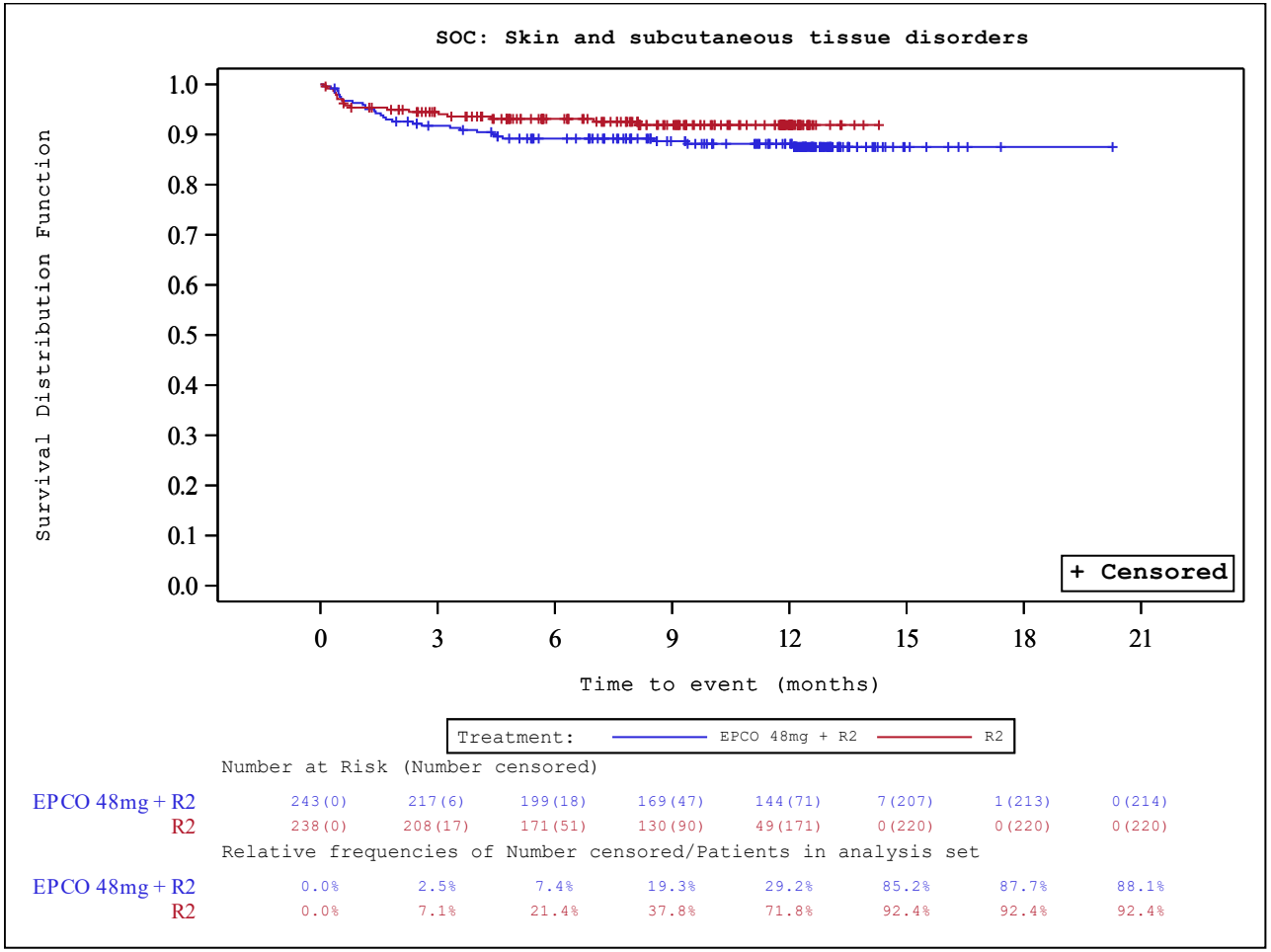
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



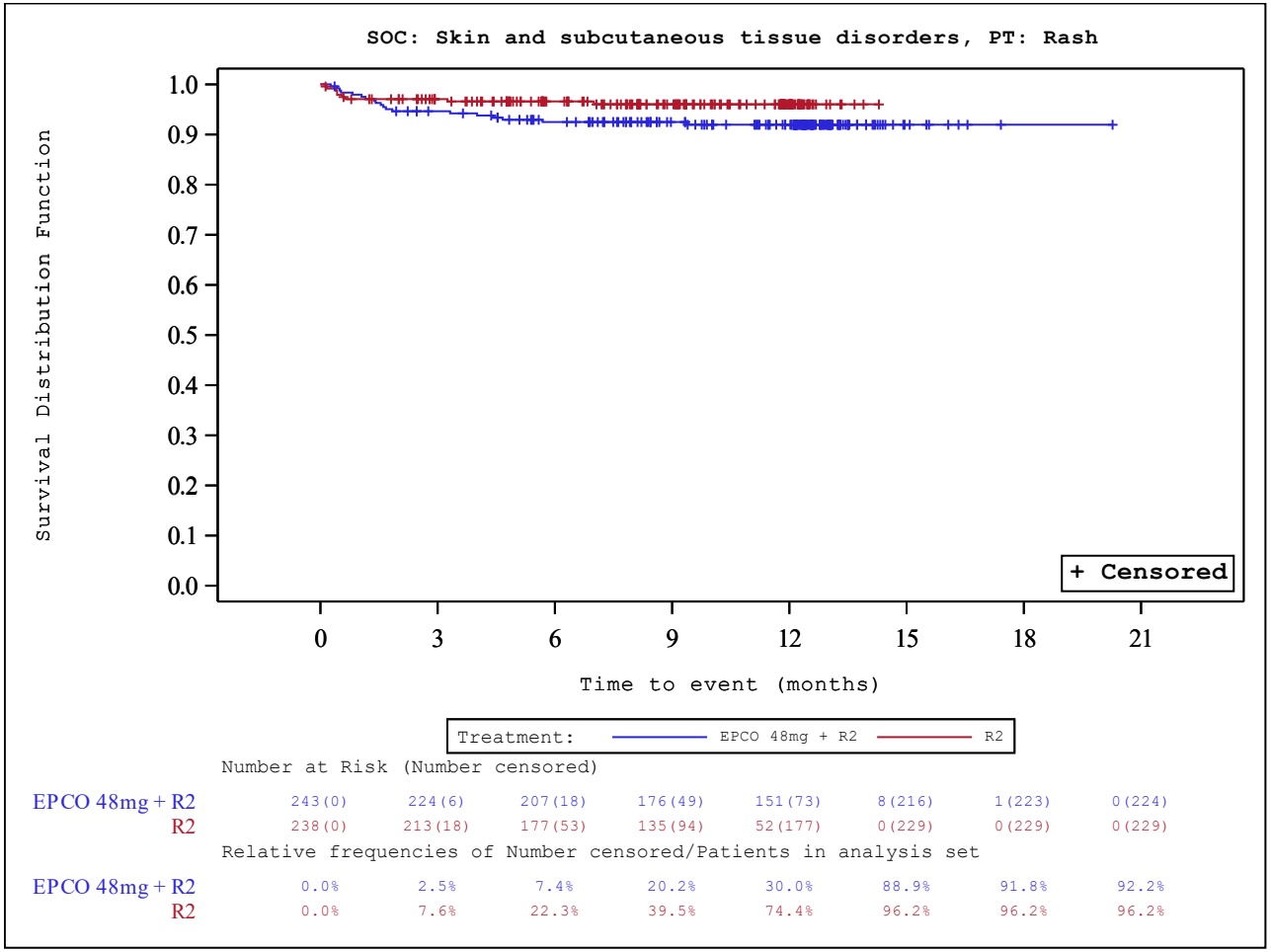
Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Figure 4.5.3 Kaplan-Meier Plot of Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)



Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Kaplan-Meier Plots for subgroups only created if p-value for interaction < 0.05.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders	Age (years)							0.1094
	<65	78/ 155 (50.3)	10.38 (4.70, NE)	34/ 137 (24.8)	NE (NE , NE)	2.30 (1.54, 3.45)	<.0001	
	>=65	52/ 88 (59.1)	6.11 (2.86, 9.26)	44/ 101 (43.6)	10.35 (7.20, NE)	1.47 (0.98, 2.19)	0.0589	
	Sex							0.2633
	Male	72/ 139 (51.8)	8.15 (5.49, NE)	46/ 135 (34.1)	NE (NE , NE)	1.59 (1.10, 2.30)	0.0126	
	Female	58/ 104 (55.8)	6.01 (3.02, NE)	32/ 103 (31.1)	NE (NE , NE)	2.18 (1.41, 3.36)	0.0003	
	Disease Status 2L							0.4378
	2L: progression of disease <= 2 years	34/ 63 (54.0)	8.38 (3.02, NE)	20/ 61 (32.8)	NE (7.85, NE)	1.62 (0.93, 2.82)	0.0820	
	2L: progression of disease > 2 years	46/ 94 (48.9)	10.12 (6.01, NE)	23/ 94 (24.5)	NE (NE , NE)	2.24 (1.36, 3.70)	0.0011	
	Disease Status 3L+							0.1113
	3L+: < 6 months	15/ 23 (65.2)	1.48 (0.53, NE)	8/ 22 (36.4)	NE (1.87, NE)	2.67 (1.12, 6.36)	0.0200	
	3L+: >= 6 months	35/ 63 (55.6)	5.06 (2.56, NE)	27/ 61 (44.3)	NE (6.01, NE)	1.36 (0.82, 2.25)	0.2227	
	Region							0.8019
	US/Western Europe	27/ 58 (46.6)	NE (5.91, NE)	14/ 57 (24.6)	NE (NE , NE)	1.96 (1.03, 3.75)	0.0362	
	Rest of world	103/ 185 (55.7)	6.51 (3.71, 10.41)	64/ 181 (35.4)	NE (NE , NE)	1.80 (1.32, 2.46)	0.0002	
	Number of prior anti-lymphoma therapies							0.5565
	2L	80/ 157 (51.0)	9.26 (6.24, NE)	43/ 155 (27.7)	NE (NE , NE)	1.98 (1.37, 2.87)	0.0002	
	3L+	50/ 86 (58.1)	3.65 (2.33, 11.07)	35/ 83 (42.2)	NE (7.20, NE)	1.65 (1.07, 2.54)	0.0211	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Lymphopenia	Age (years)							0.3235
	<65	9/ 155 (5.8)	NE (NE , NE)	1/ 137 (0.7)	NE (NE , NE)	7.82 (0.99, 61.78)	0.0206	
	>=65	6/ 88 (6.8)	NE (NE , NE)	3/ 101 (3.0)	NE (NE , NE)	2.22 (0.55, 8.90)	0.2449	
	Sex							0.6876
	Male	6/ 139 (4.3)	NE (NE , NE)	2/ 135 (1.5)	NE (NE , NE)	2.79 (0.56, 13.85)	0.1900	
	Female	9/ 104 (8.7)	NE (NE , NE)	2/ 103 (1.9)	NE (NE , NE)	4.46 (0.96, 20.64)	0.0360	
	Disease Status 2L							
	2L: progression of disease <= 2 years	3/ 63 (4.8)		1/ 61 (1.6)				
	2L: progression of disease > 2 years	7/ 94 (7.4)		0/ 94 (0.0)				
	Disease Status 3L+							
	3L+: < 6 months	0/ 23 (0.0)		0/ 22 (0.0)				
	3L+: >= 6 months	5/ 63 (7.9)		3/ 61 (4.9)				
	Region							0.9911
	US/Western Europe	4/ 58 (6.9)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
	Rest of world	11/ 185 (5.9)	NE (NE , NE)	4/ 181 (2.2)	NE (NE , NE)	2.60 (0.83, 8.17)	0.0894	
	Number of prior anti-lymphoma therapies							0.1623
	2L	10/ 157 (6.4)	NE (NE , NE)	1/ 155 (0.6)	NE (NE , NE)	9.66 (1.24, 75.51)	0.0079	
	3L+	5/ 86 (5.8)	NE (NE , NE)	3/ 83 (3.6)	NE (NE , NE)	1.59 (0.38, 6.64)	0.5239	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Age (years)							0.3167
	<65	66/ 155 (42.6)	NE (9.33, NE)	27/ 137 (19.7)	NE (NE , NE)	2.33 (1.49, 3.65)	0.0001	
	>=65	46/ 88 (52.3)	7.82 (3.71, NE)	34/ 101 (33.7)	NE (10.35, NE)	1.67 (1.07, 2.61)	0.0210	
	Sex							0.1635
	Male	61/ 139 (43.9)	NE (7.62, NE)	37/ 135 (27.4)	NE (NE , NE)	1.59 (1.06, 2.40)	0.0241	
	Female	51/ 104 (49.0)	10.41 (4.63, NE)	24/ 103 (23.3)	NE (NE , NE)	2.51 (1.54, 4.07)	0.0001	
	Disease Status 2L							0.9687
	2L: progression of disease <= 2 years	30/ 63 (47.6)	NE (5.78, NE)	15/ 61 (24.6)	NE (9.63, NE)	1.88 (1.01, 3.49)	0.0427	
	2L: progression of disease > 2 years	37/ 94 (39.4)	NE (7.82, NE)	20/ 94 (21.3)	NE (NE , NE)	1.96 (1.14, 3.37)	0.0134	
	Disease Status 3L+							0.1377
	3L+: < 6 months	12/ 23 (52.2)	3.52 (1.48, NE)	4/ 22 (18.2)	NE (NE , NE)	3.47 (1.11, 10.80)	0.0219	
	3L+: >= 6 months	33/ 63 (52.4)	10.41 (2.60, NE)	22/ 61 (36.1)	NE (7.98, NE)	1.56 (0.91, 2.69)	0.1002	
	Region							0.7837
	US/Western Europe	24/ 58 (41.4)	NE (6.51, NE)	11/ 57 (19.3)	NE (NE , NE)	2.13 (1.04, 4.35)	0.0325	
	Rest of world	88/ 185 (47.6)	12.39 (6.51, NE)	50/ 181 (27.6)	NE (NE , NE)	1.90 (1.34, 2.69)	0.0002	
	Number of prior anti-lymphoma therapies							0.9506
	2L	67/ 157 (42.7)	NE (8.38, NE)	35/ 155 (22.6)	NE (NE , NE)	1.96 (1.30, 2.94)	0.0010	
	3L+	45/ 86 (52.3)	9.23 (2.60, NE)	26/ 83 (31.3)	NE (NE , NE)	1.92 (1.18, 3.12)	0.0068	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	Age (years)							0.5806
	<65	49/ 155 (31.6)	NE (NE , NE)	18/ 137 (13.1)	12.94 (NE , NE)	2.37 (1.38, 4.07)	0.0013	
	>=65	32/ 88 (36.4)	13.73 (13.73, NE)	19/ 101 (18.8)	NE (NE , NE)	1.89 (1.07, 3.35)	0.0255	
	Sex							0.8267
	Male	45/ 139 (32.4)	NE (13.73, NE)	20/ 135 (14.8)	NE (NE , NE)	2.01 (1.19, 3.42)	0.0082	
	Female	36/ 104 (34.6)	NE (NE , NE)	17/ 103 (16.5)	NE (12.94, NE)	2.21 (1.24, 3.94)	0.0058	
	Disease Status 2L							0.0483
	2L: progression of disease <= 2 years	14/ 63 (22.2)	NE (NE , NE)	12/ 61 (19.7)	NE (NE , NE)	0.95 (0.44, 2.06)	0.8902	
	2L: progression of disease > 2 years	27/ 94 (28.7)	NE (NE , NE)	10/ 94 (10.6)	NE (NE , NE)	2.77 (1.34, 5.73)	0.0040	
	Disease Status 3L+							0.7825
	3L+: < 6 months	13/ 23 (56.5)	7.46 (1.38, 13.73)	4/ 22 (18.2)	NE (NE , NE)	3.20 (1.03, 9.93)	0.0324	
	3L+: >= 6 months	27/ 63 (42.9)	NE (9.13, NE)	11/ 61 (18.0)	NE (12.94, NE)	2.56 (1.27, 5.17)	0.0065	
	Region							0.0270
	US/Western Europe	14/ 58 (24.1)	NE (NE , NE)	12/ 57 (21.1)	NE (NE , NE)	1.05 (0.49, 2.27)	0.9004	
	Rest of world	67/ 185 (36.2)	NE (13.73, NE)	25/ 181 (13.8)	NE (12.94, NE)	2.65 (1.67, 4.19)	<.0001	
	Number of prior anti-lymphoma therapies							0.2054
	2L	41/ 157 (26.1)	NE (NE , NE)	22/ 155 (14.2)	NE (NE , NE)	1.76 (1.05, 2.96)	0.0299	
	3L+	40/ 86 (46.5)	13.73 (8.57, 13.73)	15/ 83 (18.1)	NE (12.94, NE)	2.78 (1.53, 5.04)	0.0004	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Pneumonia	Age (years)							0.7649
	<65	19/ 155 (12.3)	NE (NE , NE)	8/ 137 (5.8)	NE (NE , NE)	1.87 (0.82, 4.28)	0.1304	
	>=65	9/ 88 (10.2)	NE (NE , NE)	4/ 101 (4.0)	NE (NE , NE)	2.39 (0.73, 7.77)	0.1360	
	Sex							0.4875
	Male	20/ 139 (14.4)	NE (NE , NE)	7/ 135 (5.2)	NE (NE , NE)	2.44 (1.03, 5.78)	0.0363	
	Female	8/ 104 (7.7)	NE (NE , NE)	5/ 103 (4.9)	NE (NE , NE)	1.49 (0.49, 4.56)	0.4830	
	Disease Status 2L							0.0912
	2L: progression of disease <= 2 years	4/ 63 (6.3)	NE (NE , NE)	4/ 61 (6.6)	NE (NE , NE)	0.71 (0.17, 2.87)	0.6258	
	2L: progression of disease > 2 years	9/ 94 (9.6)	NE (NE , NE)	2/ 94 (2.1)	NE (NE , NE)	4.21 (0.91, 19.52)	0.0452	
	Disease Status 3L+							0.9961
	3L+: < 6 months	5/ 23 (21.7)	NE (NE , NE)	2/ 22 (9.1)	NE (NE , NE)	2.53 (0.49, 13.05)	0.2489	
	3L+: >= 6 months	10/ 63 (15.9)	NE (NE , NE)	4/ 61 (6.6)	NE (NE , NE)	2.30 (0.72, 7.35)	0.1471	
	Region							0.3489
	US/Western Europe	2/ 58 (3.4)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	0.97 (0.14, 6.91)	0.9785	
	Rest of world	26/ 185 (14.1)	NE (NE , NE)	10/ 181 (5.5)	NE (NE , NE)	2.30 (1.11, 4.78)	0.0213	
	Number of prior anti-lymphoma therapies							0.7603
	2L	13/ 157 (8.3)	NE (NE , NE)	6/ 155 (3.9)	NE (NE , NE)	1.83 (0.69, 4.82)	0.2157	
	3L+	15/ 86 (17.4)	NE (NE , NE)	6/ 83 (7.2)	NE (NE , NE)	2.35 (0.91, 6.05)	0.0689	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Investigations	Age (years)							0.1019
	<65	68/ 155 (43.9)	NE (7.56, NE)	32/ 137 (23.4)	NE (NE , NE)	2.07 (1.36, 3.15)	0.0005	
	>=65	23/ 88 (26.1)	NE (NE , NE)	23/ 101 (22.8)	NE (NE , NE)	1.12 (0.63, 2.00)	0.7040	
	Sex							0.1759
	Male	48/ 139 (34.5)	NE (NE , NE)	33/ 135 (24.4)	NE (NE , NE)	1.39 (0.89, 2.17)	0.1438	
	Female	43/ 104 (41.3)	NE (7.56, NE)	22/ 103 (21.4)	NE (NE , NE)	2.26 (1.35, 3.77)	0.0014	
	Disease Status 2L							0.6373
	2L: progression of disease <= 2 years	21/ 63 (33.3)	NE (NE , NE)	14/ 61 (23.0)	NE (NE , NE)	1.47 (0.75, 2.90)	0.2588	
	2L: progression of disease > 2 years	33/ 94 (35.1)	NE (NE , NE)	20/ 94 (21.3)	NE (NE , NE)	1.78 (1.02, 3.10)	0.0393	
	Disease Status 3L+							0.9672
	3L+: < 6 months	12/ 23 (52.2)	8.51 (1.87, NE)	7/ 22 (31.8)	NE (7.62, NE)	1.87 (0.73, 4.75)	0.1795	
	3L+: >= 6 months	25/ 63 (39.7)	NE (7.56, NE)	14/ 61 (23.0)	NE (NE , NE)	1.88 (0.98, 3.62)	0.0541	
	Region							0.2090
	US/Western Europe	15/ 58 (25.9)	NE (NE , NE)	13/ 57 (22.8)	NE (NE , NE)	1.11 (0.53, 2.34)	0.7771	
	Rest of world	76/ 185 (41.1)	NE (NE , NE)	42/ 181 (23.2)	NE (NE , NE)	1.92 (1.32, 2.80)	0.0005	
	Number of prior anti-lymphoma therapies							0.6987
	2L	54/ 157 (34.4)	NE (NE , NE)	34/ 155 (21.9)	NE (NE , NE)	1.63 (1.06, 2.51)	0.0239	
	3L+	37/ 86 (43.0)	NE (7.56, NE)	21/ 83 (25.3)	NE (NE , NE)	1.88 (1.10, 3.22)	0.0183	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Investigations, PT: Alanine aminotransferase increased	Age (years)							0.9924
	<65	14/ 155 (9.0)	NE (NE , NE)	2/ 137 (1.5)	NE (NE , NE)	6.07 (1.38, 26.73)	0.0065	
	>=65	1/ 88 (1.1)	NE (NE , NE)	0/ 101 (0.0)	NE (NE , NE)	NE		
	Sex							0.4784
	Male	4/ 139 (2.9)	NE (NE , NE)	1/ 135 (0.7)	NE (NE , NE)	3.55 (0.39, 31.90)	0.2278	
	Female	11/ 104 (10.6)	NE (NE , NE)	1/ 103 (1.0)	NE (NE , NE)	11.06 (1.43, 85.68)	0.0037	
	Disease Status 2L							
	2L: progression of disease <= 2 years	6/ 63 (9.5)		1/ 61 (1.6)				
	2L: progression of disease > 2 years	4/ 94 (4.3)		1/ 94 (1.1)				
	Disease Status 3L+							
	3L+: < 6 months	2/ 23 (8.7)		0/ 22 (0.0)				
	3L+: >= 6 months	3/ 63 (4.8)		0/ 61 (0.0)				
	Region							0.9936
	US/Western Europe	1/ 58 (1.7)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE		
	Rest of world	14/ 185 (7.6)	NE (NE , NE)	2/ 181 (1.1)	NE (NE , NE)	6.76 (1.53, 29.75)	0.0034	
	Number of prior anti-lymphoma therapies							0.9907
	2L	10/ 157 (6.4)	NE (NE , NE)	2/ 155 (1.3)	NE (NE , NE)	4.87 (1.07, 22.25)	0.0236	
	3L+	5/ 86 (5.8)	NE (NE , NE)	0/ 83 (0.0)	NE (NE , NE)	NE		

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

AbbVie
Epcoritamab - Study M20-638 - data cutoff date: 24 MAY 2025
Study population: Safety Analysis Set
Table 4.5.3.S Time to first frequent Severe Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis

SOC/PT	Subgroup Level	EPCO 48mg + R2 (N=243) n/ N (%)	EPCO 48mg + R2 (N=243) Median (95%-CI)	R2 (N=238) n/ N (%)	R2 (N=238) Median (95%-CI)	EPCO 48mg + R2 vs. R2 Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Metabolism and nutrition disorders	Age (years)							0.1100
	<65	20/ 155 (12.9)	NE (NE , NE)	3/ 137 (2.2)	NE (NE , NE)	5.82 (1.73, 19.59)	0.0013	
	>=65	10/ 88 (11.4)	NE (NE , NE)	7/ 101 (6.9)	NE (NE , NE)	1.66 (0.63, 4.36)	0.2992	
	Sex							0.6728
	Male	15/ 139 (10.8)	NE (NE , NE)	4/ 135 (3.0)	NE (NE , NE)	3.52 (1.17, 10.61)	0.0172	
	Female	15/ 104 (14.4)	NE (NE , NE)	6/ 103 (5.8)	NE (NE , NE)	2.57 (1.00, 6.63)	0.0425	
	Disease Status 2L							0.5477
	2L: progression of disease <= 2 years	11/ 63 (17.5)	NE (NE , NE)	3/ 61 (4.9)	NE (NE , NE)	3.45 (0.96, 12.37)	0.0431	
	2L: progression of disease > 2 years	8/ 94 (8.5)	NE (NE , NE)	4/ 94 (4.3)	NE (NE , NE)	1.99 (0.60, 6.61)	0.2513	
	Disease Status 3L+							0.9922
	3L+: < 6 months	4/ 23 (17.4)	NE (NE , NE)	0/ 22 (0.0)	NE (NE , NE)	NE		
	3L+: >= 6 months	7/ 63 (11.1)	NE (NE , NE)	3/ 61 (4.9)	NE (NE , NE)	2.21 (0.57, 8.56)	0.2378	
	Region							0.9574
	US/Western Europe	9/ 58 (15.5)	NE (NE , NE)	3/ 57 (5.3)	NE (NE , NE)	2.99 (0.81, 11.07)	0.0841	
	Rest of world	21/ 185 (11.4)	NE (NE , NE)	7/ 181 (3.9)	NE (NE , NE)	2.89 (1.23, 6.81)	0.0108	
	Number of prior anti-lymphoma therapies							0.6903
	2L	19/ 157 (12.1)	NE (NE , NE)	7/ 155 (4.5)	NE (NE , NE)	2.65 (1.11, 6.30)	0.0219	
	3L+	11/ 86 (12.8)	NE (NE , NE)	3/ 83 (3.6)	NE (NE , NE)	3.53 (0.98, 12.67)	0.0387	

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on hazard ratio or, if hazard ratio not estimable, based on relative risk (alpha=0.05).
Median is Kaplan-Meier estimate.
Hazard ratios and 95% CIs are estimated using Cox proportional hazards model, p-value for hazard ratio is estimated using a two-sided log-rank test.
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-Value for interaction is estimated using Cox Proportional Hazard Model with additional factors for subgroup and treatment-by-subgroup interaction.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.6.1 Incidence of Adverse Events leading to discontinuation of Epcoritamab by SOC and PT

SOC / PT	EPCO 48mg + R2 (N=243)	R2 (N=238)
Blood and lymphatic system disorders	2/243 (0.8)	0/238 (0.0)
Anaemia	1/243 (0.4)	0/238 (0.0)
Neutropenia	1/243 (0.4)	0/238 (0.0)
Cardiac disorders	3/243 (1.2)	0/238 (0.0)
Cardiac arrest	1/243 (0.4)	0/238 (0.0)
Cardiac failure	1/243 (0.4)	0/238 (0.0)
Myocardial infarction	1/243 (0.4)	0/238 (0.0)
Myocardial ischaemia	1/243 (0.4)	0/238 (0.0)
Gastrointestinal disorders	1/243 (0.4)	0/238 (0.0)
Diarrhoea	1/243 (0.4)	0/238 (0.0)
General disorders and administration site conditions	4/243 (1.6)	0/238 (0.0)
Asthenia	1/243 (0.4)	0/238 (0.0)
General physical health deterioration	1/243 (0.4)	0/238 (0.0)
Injection site reaction	1/243 (0.4)	0/238 (0.0)
Multiple organ dysfunction syndrome	1/243 (0.4)	0/238 (0.0)
Pyrexia	1/243 (0.4)	0/238 (0.0)
Infections and infestations	12/243 (4.9)	0/238 (0.0)
Bronchopulmonary aspergillosis	1/243 (0.4)	0/238 (0.0)
COVID-19	1/243 (0.4)	0/238 (0.0)
COVID-19 pneumonia	2/243 (0.8)	0/238 (0.0)
Cytomegalovirus viraemia	1/243 (0.4)	0/238 (0.0)
Endocarditis staphylococcal	1/243 (0.4)	0/238 (0.0)
Infection	1/243 (0.4)	0/238 (0.0)
Pneumonia	4/243 (1.6)	0/238 (0.0)
Pneumonia cytomegaloviral	1/243 (0.4)	0/238 (0.0)
Rhinovirus infection	1/243 (0.4)	0/238 (0.0)
Upper respiratory tract infection	1/243 (0.4)	0/238 (0.0)
Investigations	2/243 (0.8)	0/238 (0.0)
Alanine aminotransferase increased	1/243 (0.4)	0/238 (0.0)
Blood bilirubin increased	1/243 (0.4)	0/238 (0.0)
Blood uric acid increased	1/243 (0.4)	0/238 (0.0)
Lymphocyte count decreased	1/243 (0.4)	0/238 (0.0)
Neutrophil count decreased	1/243 (0.4)	0/238 (0.0)
Platelet count decreased	1/243 (0.4)	0/238 (0.0)
White blood cell count decreased	1/243 (0.4)	0/238 (0.0)
Metabolism and nutrition disorders	1/243 (0.4)	0/238 (0.0)
Hypoalbuminaemia	1/243 (0.4)	0/238 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/243 (0.4)	0/238 (0.0)
Malignant neoplasm of unknown primary site	1/243 (0.4)	0/238 (0.0)
Respiratory, thoracic and mediastinal disorders	3/243 (1.2)	0/238 (0.0)
Bronchopneumopathy	1/243 (0.4)	0/238 (0.0)
Cough	1/243 (0.4)	0/238 (0.0)
Pulmonary embolism	1/243 (0.4)	0/238 (0.0)
Skin and subcutaneous tissue disorders	1/243 (0.4)	0/238 (0.0)

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.6.1 Incidence of Adverse Events leading to discontinuation of Epcoritamab by SOC and PT

SOC / PT	EPCO 48mg + R2 (N=243)	R2 (N=238)
Rash	1/243 (0.4)	0/238 (0.0)
Vascular disorders	1/243 (0.4)	0/238 (0.0)
Shock	1/243 (0.4)	0/238 (0.0)

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.6.2 Incidence of Adverse Events leading to discontinuation of Rituximab by SOC and PT

SOC / PT	EPCO 48mg + R2 (N=243)	R2 (N=238)
Blood and lymphatic system disorders	0/243 (0.0)	2/238 (0.8)
Febrile neutropenia	0/243 (0.0)	1/238 (0.4)
Neutropenia	0/243 (0.0)	1/238 (0.4)
Cardiac disorders	2/243 (0.8)	1/238 (0.4)
Cardiac arrest	1/243 (0.4)	0/238 (0.0)
Myocardial infarction	1/243 (0.4)	0/238 (0.0)
Myocardial ischaemia	1/243 (0.4)	0/238 (0.0)
Stress cardiomyopathy	0/243 (0.0)	1/238 (0.4)
General disorders and administration site conditions	1/243 (0.4)	0/238 (0.0)
General physical health deterioration	1/243 (0.4)	0/238 (0.0)
Infections and infestations	2/243 (0.8)	2/238 (0.8)
Bronchiolitis	0/243 (0.0)	1/238 (0.4)
Pneumonia	1/243 (0.4)	0/238 (0.0)
Sinusitis	1/243 (0.4)	0/238 (0.0)
Skin infection	0/243 (0.0)	1/238 (0.4)
Injury, poisoning and procedural complications	0/243 (0.0)	1/238 (0.4)
Subdural haematoma	0/243 (0.0)	1/238 (0.4)
Investigations	1/243 (0.4)	0/238 (0.0)
Alanine aminotransferase increased	1/243 (0.4)	0/238 (0.0)
Metabolism and nutrition disorders	0/243 (0.0)	1/238 (0.4)
Decreased appetite	0/243 (0.0)	1/238 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/243 (0.4)	3/238 (1.3)
Malignant neoplasm of unknown primary site	1/243 (0.4)	0/238 (0.0)
Malignant neoplasm progression	0/243 (0.0)	2/238 (0.8)
Squamous cell carcinoma of the parotid gland	0/243 (0.0)	1/238 (0.4)
Renal and urinary disorders	0/243 (0.0)	1/238 (0.4)
End stage renal disease	0/243 (0.0)	1/238 (0.4)
Respiratory, thoracic and mediastinal disorders	0/243 (0.0)	1/238 (0.4)
Pleural effusion	0/243 (0.0)	1/238 (0.4)

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.6.3 Incidence of Adverse Events leading to discontinuation of Lenalidomide by SOC and PT

SOC / PT	EPCO 48mg + R2 (N=243)	R2 (N=238)
Blood and lymphatic system disorders	9/243 (3.7)	5/238 (2.1)
Anaemia	1/243 (0.4)	0/238 (0.0)
Disseminated intravascular coagulation	1/243 (0.4)	0/238 (0.0)
Febrile neutropenia	1/243 (0.4)	1/238 (0.4)
Neutropenia	6/243 (2.5)	3/238 (1.3)
Thrombocytopenia	1/243 (0.4)	1/238 (0.4)
Cardiac disorders	3/243 (1.2)	1/238 (0.4)
Cardiac arrest	1/243 (0.4)	0/238 (0.0)
Cardiac failure	1/243 (0.4)	0/238 (0.0)
Myocardial infarction	1/243 (0.4)	0/238 (0.0)
Myocardial ischaemia	1/243 (0.4)	0/238 (0.0)
Stress cardiomyopathy	0/243 (0.0)	1/238 (0.4)
Eye disorders	1/243 (0.4)	0/238 (0.0)
Periorbital oedema	1/243 (0.4)	0/238 (0.0)
Gastrointestinal disorders	4/243 (1.6)	3/238 (1.3)
Abdominal pain	1/243 (0.4)	0/238 (0.0)
Abdominal wall haematoma	0/243 (0.0)	1/238 (0.4)
Colitis ischaemic	0/243 (0.0)	1/238 (0.4)
Diarrhoea	3/243 (1.2)	1/238 (0.4)
General disorders and administration site conditions	6/243 (2.5)	2/238 (0.8)
Asthenia	1/243 (0.4)	0/238 (0.0)
Death	0/243 (0.0)	1/238 (0.4)
Fatigue	1/243 (0.4)	0/238 (0.0)
General physical health deterioration	1/243 (0.4)	0/238 (0.0)
Injection site reaction	1/243 (0.4)	0/238 (0.0)
Multiple organ dysfunction syndrome	1/243 (0.4)	0/238 (0.0)
Pyrexia	1/243 (0.4)	0/238 (0.0)
Sudden death	0/243 (0.0)	1/238 (0.4)
Swelling face	1/243 (0.4)	0/238 (0.0)
Infections and infestations	13/243 (5.3)	3/238 (1.3)
Bronchiolitis	0/243 (0.0)	1/238 (0.4)
Bronchitis	1/243 (0.4)	0/238 (0.0)
Bronchopulmonary aspergillosis	1/243 (0.4)	0/238 (0.0)
COVID-19	1/243 (0.4)	0/238 (0.0)
COVID-19 pneumonia	2/243 (0.8)	0/238 (0.0)
Campylobacter infection	1/243 (0.4)	0/238 (0.0)
Encephalitis	0/243 (0.0)	1/238 (0.4)
Endocarditis staphylococcal	1/243 (0.4)	0/238 (0.0)
Infection	1/243 (0.4)	0/238 (0.0)
Pneumonia	4/243 (1.6)	0/238 (0.0)
Pneumonia cytomegaloviral	1/243 (0.4)	0/238 (0.0)
Rhinovirus infection	1/243 (0.4)	0/238 (0.0)
Skin infection	0/243 (0.0)	1/238 (0.4)
Upper respiratory tract infection	1/243 (0.4)	0/238 (0.0)
West Nile viral infection	0/243 (0.0)	1/238 (0.4)
Injury, poisoning and procedural complications	0/243 (0.0)	1/238 (0.4)
Subdural haematoma	0/243 (0.0)	1/238 (0.4)

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.6.3 Incidence of Adverse Events leading to discontinuation of Lenalidomide by SOC and PT

SOC / PT	EPCO 48mg + R2 (N=243)	R2 (N=238)
Investigations	3/243 (1.2)	2/238 (0.8)
Alanine aminotransferase increased	1/243 (0.4)	0/238 (0.0)
Blood bilirubin increased	1/243 (0.4)	0/238 (0.0)
Blood creatinine increased	2/243 (0.8)	0/238 (0.0)
Blood uric acid increased	1/243 (0.4)	0/238 (0.0)
Lymphocyte count decreased	1/243 (0.4)	0/238 (0.0)
Neutrophil count decreased	1/243 (0.4)	2/238 (0.8)
Platelet count decreased	1/243 (0.4)	0/238 (0.0)
White blood cell count decreased	1/243 (0.4)	0/238 (0.0)
Metabolism and nutrition disorders	2/243 (0.8)	1/238 (0.4)
Decreased appetite	0/243 (0.0)	1/238 (0.4)
Hypoalbuminaemia	1/243 (0.4)	0/238 (0.0)
Hypomagnesaemia	1/243 (0.4)	0/238 (0.0)
Musculoskeletal and connective tissue disorders	1/243 (0.4)	1/238 (0.4)
Arthralgia	1/243 (0.4)	0/238 (0.0)
Bone pain	0/243 (0.0)	1/238 (0.4)
Myalgia	0/243 (0.0)	1/238 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/243 (0.4)	3/238 (1.3)
Malignant neoplasm of unknown primary site	1/243 (0.4)	0/238 (0.0)
Malignant neoplasm progression	0/243 (0.0)	2/238 (0.8)
Squamous cell carcinoma of the parotid gland	0/243 (0.0)	1/238 (0.4)
Nervous system disorders	1/243 (0.4)	0/238 (0.0)
Peripheral sensory neuropathy	1/243 (0.4)	0/238 (0.0)
Renal and urinary disorders	1/243 (0.4)	1/238 (0.4)
End stage renal disease	0/243 (0.0)	1/238 (0.4)
Renal impairment	1/243 (0.4)	0/238 (0.0)
Respiratory, thoracic and mediastinal disorders	4/243 (1.6)	3/238 (1.3)
Bronchopneumopathy	1/243 (0.4)	0/238 (0.0)
Cough	1/243 (0.4)	0/238 (0.0)
Pleural effusion	0/243 (0.0)	1/238 (0.4)
Pulmonary embolism	2/243 (0.8)	2/238 (0.8)
Skin and subcutaneous tissue disorders	9/243 (3.7)	2/238 (0.8)
Dermatitis	1/243 (0.4)	0/238 (0.0)
Eczema	1/243 (0.4)	0/238 (0.0)
Rash	4/243 (1.6)	2/238 (0.8)
Rash macular	1/243 (0.4)	0/238 (0.0)
Rash maculo-papular	1/243 (0.4)	0/238 (0.0)
Rash papular	1/243 (0.4)	0/238 (0.0)
Vascular disorders	1/243 (0.4)	1/238 (0.4)
Deep vein thrombosis	0/243 (0.0)	1/238 (0.4)
Shock	1/243 (0.4)	0/238 (0.0)

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.6.4 Incidence of Adverse Events leading to discontinuation of any Study Drug by SOC and PT

SOC / PT	EPCO 48mg + R2 (N=243)	R2 (N=238)
Blood and lymphatic system disorders	9/243 (3.7)	5/238 (2.1)
Anaemia	1/243 (0.4)	0/238 (0.0)
Disseminated intravascular coagulation	1/243 (0.4)	0/238 (0.0)
Febrile neutropenia	1/243 (0.4)	1/238 (0.4)
Neutropenia	6/243 (2.5)	3/238 (1.3)
Thrombocytopenia	1/243 (0.4)	1/238 (0.4)
Cardiac disorders	3/243 (1.2)	1/238 (0.4)
Cardiac arrest	1/243 (0.4)	0/238 (0.0)
Cardiac failure	1/243 (0.4)	0/238 (0.0)
Myocardial infarction	1/243 (0.4)	0/238 (0.0)
Myocardial ischaemia	1/243 (0.4)	0/238 (0.0)
Stress cardiomyopathy	0/243 (0.0)	1/238 (0.4)
Eye disorders	1/243 (0.4)	0/238 (0.0)
Periorbital oedema	1/243 (0.4)	0/238 (0.0)
Gastrointestinal disorders	4/243 (1.6)	3/238 (1.3)
Abdominal pain	1/243 (0.4)	0/238 (0.0)
Abdominal wall haematoma	0/243 (0.0)	1/238 (0.4)
Colitis ischaemic	0/243 (0.0)	1/238 (0.4)
Diarrhoea	3/243 (1.2)	1/238 (0.4)
General disorders and administration site conditions	6/243 (2.5)	2/238 (0.8)
Asthenia	1/243 (0.4)	0/238 (0.0)
Death	0/243 (0.0)	1/238 (0.4)
Fatigue	1/243 (0.4)	0/238 (0.0)
General physical health deterioration	1/243 (0.4)	0/238 (0.0)
Injection site reaction	1/243 (0.4)	0/238 (0.0)
Multiple organ dysfunction syndrome	1/243 (0.4)	0/238 (0.0)
Pyrexia	1/243 (0.4)	0/238 (0.0)
Sudden death	0/243 (0.0)	1/238 (0.4)
Swelling face	1/243 (0.4)	0/238 (0.0)
Infections and infestations	15/243 (6.2)	3/238 (1.3)
Bronchiolitis	0/243 (0.0)	1/238 (0.4)
Bronchitis	1/243 (0.4)	0/238 (0.0)
Bronchopulmonary aspergillosis	1/243 (0.4)	0/238 (0.0)
COVID-19	1/243 (0.4)	0/238 (0.0)
COVID-19 pneumonia	2/243 (0.8)	0/238 (0.0)
Campylobacter infection	1/243 (0.4)	0/238 (0.0)
Cytomegalovirus viraemia	1/243 (0.4)	0/238 (0.0)
Encephalitis	0/243 (0.0)	1/238 (0.4)
Endocarditis staphylococcal	1/243 (0.4)	0/238 (0.0)
Infection	1/243 (0.4)	0/238 (0.0)
Pneumonia	4/243 (1.6)	0/238 (0.0)
Pneumonia cytomegaloviral	1/243 (0.4)	0/238 (0.0)
Rhinovirus infection	1/243 (0.4)	0/238 (0.0)
Sinusitis	1/243 (0.4)	0/238 (0.0)
Skin infection	0/243 (0.0)	1/238 (0.4)
Upper respiratory tract infection	1/243 (0.4)	0/238 (0.0)
West Nile viral infection	0/243 (0.0)	1/238 (0.4)

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.

Table 4.6.4 Incidence of Adverse Events leading to discontinuation of any Study Drug by SOC and PT

SOC / PT	EPCO 48mg + R2 (N=243)	R2 (N=238)
Injury, poisoning and procedural complications	0/243 (0.0)	1/238 (0.4)
Subdural haematoma	0/243 (0.0)	1/238 (0.4)
Investigations	3/243 (1.2)	2/238 (0.8)
Alanine aminotransferase increased	1/243 (0.4)	0/238 (0.0)
Blood bilirubin increased	1/243 (0.4)	0/238 (0.0)
Blood creatinine increased	2/243 (0.8)	0/238 (0.0)
Blood uric acid increased	1/243 (0.4)	0/238 (0.0)
Lymphocyte count decreased	1/243 (0.4)	0/238 (0.0)
Neutrophil count decreased	1/243 (0.4)	2/238 (0.8)
Platelet count decreased	1/243 (0.4)	0/238 (0.0)
White blood cell count decreased	1/243 (0.4)	0/238 (0.0)
Metabolism and nutrition disorders	2/243 (0.8)	1/238 (0.4)
Decreased appetite	0/243 (0.0)	1/238 (0.4)
Hypoalbuminaemia	1/243 (0.4)	0/238 (0.0)
Hypomagnesaemia	1/243 (0.4)	0/238 (0.0)
Musculoskeletal and connective tissue disorders	1/243 (0.4)	1/238 (0.4)
Arthralgia	1/243 (0.4)	0/238 (0.0)
Bone pain	0/243 (0.0)	1/238 (0.4)
Myalgia	0/243 (0.0)	1/238 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/243 (0.4)	3/238 (1.3)
Malignant neoplasm of unknown primary site	1/243 (0.4)	0/238 (0.0)
Malignant neoplasm progression	0/243 (0.0)	2/238 (0.8)
Squamous cell carcinoma of the parotid gland	0/243 (0.0)	1/238 (0.4)
Nervous system disorders	1/243 (0.4)	0/238 (0.0)
Peripheral sensory neuropathy	1/243 (0.4)	0/238 (0.0)
Renal and urinary disorders	1/243 (0.4)	1/238 (0.4)
End stage renal disease	0/243 (0.0)	1/238 (0.4)
Renal impairment	1/243 (0.4)	0/238 (0.0)
Respiratory, thoracic and mediastinal disorders	4/243 (1.6)	3/238 (1.3)
Bronchopneumopathy	1/243 (0.4)	0/238 (0.0)
Cough	1/243 (0.4)	0/238 (0.0)
Pleural effusion	0/243 (0.0)	1/238 (0.4)
Pulmonary embolism	2/243 (0.8)	2/238 (0.8)
Skin and subcutaneous tissue disorders	9/243 (3.7)	2/238 (0.8)
Dermatitis	1/243 (0.4)	0/238 (0.0)
Eczema	1/243 (0.4)	0/238 (0.0)
Rash	4/243 (1.6)	2/238 (0.8)
Rash macular	1/243 (0.4)	0/238 (0.0)
Rash maculo-papular	1/243 (0.4)	0/238 (0.0)
Rash papular	1/243 (0.4)	0/238 (0.0)
Vascular disorders	1/243 (0.4)	1/238 (0.4)
Deep vein thrombosis	0/243 (0.0)	1/238 (0.4)
Shock	1/243 (0.4)	0/238 (0.0)

Defining TEAEs: any AE with the onset that is the first dose of study drug date until 30 days after discontinuation of lenalidomide or 60 days after discontinuation of rituximab/epcoritamab, whichever is later or until the subject begins new anti-lymphoma therapy, whichever comes first.
25th quantile, Median and 75th quantile are Kaplan-Meier estimates.
Hazard ratios and 95% CIs are estimated using a unstratified Cox proportional hazards model
Hazard ratios < 1 indicate a positive treatment effect in favor of Epcoritamab 48 mg with R2.
p-value for hazard ratio is estimated using a two-sided log-rank test.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR=Hazard Ratio; NE=Not estimable.