Dossier zur Nutzenbewertung gemäß § 35a SGB V

Inebilizumab (Uplizna®)

Amgen GmbH

Anhang 4-G zu Modul 4 C

Zusatzbehandlung zur Standardtherapie von Erwachsenen mit generalisierter Myasthenia gravis, die AChR-Antikörper- oder MuSK-Antikörper-positiv sind

Stand: 05.03.2026

Inhaltsverzeichnis

Seite

Modul 4 C, Anhang 4-G

1 Subgruppenanalysen

1.1 Todesfälle

1.1.1 Todesfälle

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio Pt Est	Odds Ratio (95% CI)	Risk Ratio Pt Est	Risk Ratio (95% CI)	Risk Difference (%) Pt Est	Risk Difference (%) (95% CI)	p-value
AChR+ Population (Week 52)									
Age									NA
>= 18 - < 65 years	1 / 81 (1.2)	1 / 76 (1.3)	NA	NA	NA	NA	NA	NA	NA
>= 65 years	1 / 14 (7.1)	0 / 19 (0.0)	NA	NA	NA	NA	NA	NA	NA
Sex									NA
Male	2 / 46 (4.3)	1 / 35 (2.9)	NA	NA	NA	NA	NA	NA	NA
Female	0 / 49 (0.0)	0 / 60 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline steroid use									NA
Prednisone <= 20 mg/day	0 / 55 (0.0)	0 / 63 (0.0)	NA	NA	NA	NA	NA	NA	NA
Prednisone > 20 mg/day	2 / 31 (6.5)	1 / 27 (3.7)	NA	NA	NA	NA	NA	NA	NA
Baseline QMG									NA
QMG <= 15	0 / 39 (0.0)	0 / 38 (0.0)	NA	NA	NA	NA	NA	NA	NA
QMG >= 16	2 / 53 (3.8)	1 / 55 (1.8)	NA	NA	NA	NA	NA	NA	NA
Baseline MGFA class									NA
II	2 / 36 (5.6)	0 / 43 (0.0)	NA	NA	NA	NA	NA	NA	NA
III	0 / 49 (0.0)	1 / 49 (2.0)	NA	NA	NA	NA	NA	NA	NA
IV	0 / 8 (0.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	2 / 40 (5.0)	1 / 30 (3.3)	NA	NA	NA	NA	NA	NA	NA
Europe	0 / 40 (0.0)	0 / 37 (0.0)	NA	NA	NA	NA	NA	NA	NA
North America	0 / 12 (0.0)	0 / 19 (0.0)	NA	NA	NA	NA	NA	NA	NA
Rest of the world	0 / 3 (0.0)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
EU	0 / 40 (0.0)	0 / 37 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-EU	2 / 55 (3.6)	1 / 58 (1.7)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Japan	0 / 1 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	2 / 94 (2.1)	1 / 94 (1.1)	NA	NA	NA	NA	NA	NA	NA

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	0 / 22 (0.0)	0 / 21 (0.0)	NA	NA	NA	NA	NA	NA	NA
>= 65 years	0 / 2 (0.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	NA
Sex									NA
Male	0 / 7 (0.0)	0 / 5 (0.0)	NA	NA	NA	NA	NA	NA	NA
Female	0 / 17 (0.0)	0 / 19 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline steroid use									NA
Prednisone <= 20 mg/day	0 / 13 (0.0)	0 / 19 (0.0)	NA	NA	NA	NA	NA	NA	NA
Prednisone > 20 mg/day	0 / 10 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline QMG									NA
QMG <= 15	0 / 9 (0.0)	0 / 13 (0.0)	NA	NA	NA	NA	NA	NA	NA
QMG >= 16	0 / 15 (0.0)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline MGFA class									NA
II	0 / 12 (0.0)	0 / 13 (0.0)	NA	NA	NA	NA	NA	NA	NA
III	0 / 12 (0.0)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	NA
IV	0 / 0 (-)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	0 / 15 (0.0)	0 / 14 (0.0)	NA	NA	NA	NA	NA	NA	NA
Europe	0 / 2 (0.0)	0 / 7 (0.0)	NA	NA	NA	NA	NA	NA	NA
North America	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Rest of the world	0 / 5 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
EU	0 / 2 (0.0)	0 / 7 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-EU	0 / 22 (0.0)	0 / 17 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Japan	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	0 / 22 (0.0)	0 / 22 (0.0)	NA	NA	NA	NA	NA	NA	NA

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log. n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level. Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject). 95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios. If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.									

1.2 Myasthenia gravis Activities of Daily Living (MG-ADL)

1.2.1 Anteil an Patientinnen und Patienten mit einer Verbesserung des MG-ADL um ≥ 4 Punkte (keine Rescue-Therapie)

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									0.6164
>= 18 - < 65 years	22 / 69 (31.9)	47 / 63 (74.6)	6.00 (2.80, 12.87)	<0.0001	2.34 (1.64, 3.45)	<0.0001	42.01 (26.31, 57.71)	<0.0001	
>= 65 years	3 / 10 (30.0)	9 / 16 (56.3)	4.09 (0.55, 30.32)	0.1687	1.88 (0.76, 5.56)	0.2475	31.04 (-7.95, 70.02)	0.1187	
Sex									0.7211
Male	13 / 39 (33.3)	18 / 27 (66.7)	3.22 (1.11, 9.32)	0.0308	2.00 (1.20, 3.41)	0.0119	28.44 (3.98, 52.91)	0.0227	
Female	12 / 40 (30.0)	38 / 52 (73.1)	6.23 (2.45, 15.86)	0.0001	2.44 (1.54, 4.13)	<0.0001	42.56 (23.84, 61.29)	<0.0001	
Baseline steroid use									0.7057
Prednisone <= 20 mg/day	18 / 47 (38.3)	41 / 52 (78.8)	5.54 (2.28, 13.43)	0.0002	2.06 (1.44, 3.12)	<0.0001	39.88 (21.42, 58.33)	<0.0001	
Prednisone > 20 mg/day	7 / 27 (25.9)	14 / 24 (58.3)	3.23 (0.97, 10.77)	0.0561	2.25 (1.14, 4.71)	0.0249	28.07 (-1.01, 57.14)	0.0585	
Baseline QMG									0.2926
QMG <= 15	11 / 31 (35.5)	18 / 29 (62.1)	3.10 (1.03, 9.28)	0.0436	1.75 (1.03, 3.11)	0.0695	27.03 (1.78, 52.27)	0.0359	
QMG >= 16	14 / 46 (30.4)	36 / 48 (75.0)	6.70 (2.66, 16.92)	<0.0001	2.46 (1.60, 4.02)	<0.0001	44.20 (25.55, 62.85)	<0.0001	
Baseline MGFA class									0.3482
II	11 / 29 (37.9)	23 / 35 (65.7)	2.71 (0.95, 7.71)	0.0621	1.73 (1.06, 3.02)	0.0435	24.20 (-0.42, 48.82)	0.0540	
III	13 / 42 (31.0)	31 / 41 (75.6)	6.69 (2.47, 18.17)	0.0002	2.44 (1.56, 4.06)	<0.0001	43.69 (23.57, 63.80)	<0.0001	
IV	0 / 7 (0.0)	2 / 3 (66.7)	ND	ND	10.00 (1.14, 100.51)	0.0667	ND	ND	
Region									0.1490
Asia	14 / 32 (43.8)	17 / 26 (65.4)	2.43 (0.80, 7.39)	0.1191	1.49 (0.92, 2.47)	0.1195	21.65 (-4.88, 48.19)	0.1097	
Europe	6 / 33 (18.2)	24 / 32 (75.0)	10.41 (3.17, 34.19)	0.0001	4.13 (2.09, 8.90)	<0.0001	49.30 (26.68, 71.92)	<0.0001	

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
North America	5 / 11 (45.5)	10 / 14 (71.4)	2.72 (0.50, 14.76)	0.2452	1.57 (0.81, 3.53)	0.2406	23.79 (-15.02, 62.61)	0.2296	
Rest of the world	0 / 3 (0.0)	5 / 7 (71.4)	ND	ND	5.50 (0.93, 53.27)	0.1667	ND	ND	
Region									0.0764
EU	6 / 33 (18.2)	24 / 32 (75.0)	10.41 (3.17, 34.19)	0.0001	4.13 (2.09, 8.90)	<0.0001	49.30 (26.68, 71.92)	<0.0001	
Non-EU	19 / 46 (41.3)	32 / 47 (68.1)	2.92 (1.24, 6.90)	0.0142	1.65 (1.13, 2.50)	0.0126	26.17 (6.19, 46.15)	0.0103	
Region									NA
Japan	0 / 1 (0.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	25 / 78 (32.1)	55 / 78 (70.5)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	9 / 22 (40.9)	11 / 21 (52.4)	NA	NA	NA	NA	NA	NA	
>= 65 years	0 / 2 (0.0)	2 / 3 (66.7)	NA	NA	NA	NA	NA	NA	
Sex									0.2433
Male	4 / 7 (57.1)	2 / 5 (40.0)	0.62 (0.04, 8.58)	0.7205	0.70 (0.19, 2.17)	1.0000	-11.68 (-74.86, 51.50)	0.7171	
Female	5 / 17 (29.4)	11 / 19 (57.9)	3.37 (0.75, 15.22)	0.1139	1.97 (0.91, 4.66)	0.1065	27.35 (-4.40, 59.11)	0.0914	
Baseline steroid use									0.8704
Prednisone <= 20 mg/day	3 / 13 (23.1)	10 / 19 (52.6)	2.83 (0.60, 13.38)	0.1885	2.28 (0.88, 6.85)	0.1469	23.28 (-9.50, 56.05)	0.1639	
Prednisone > 20 mg/day	5 / 10 (50.0)	2 / 2 (100.0)	14.76 (0.18, 1241.43)	0.2339	1.67 (0.56, 3.63)	0.4697	45.41 (-1.94, 92.75)	0.0602	
Baseline QMG									1.0000
QMG <= 15	3 / 9 (33.3)	6 / 13 (46.2)	1.56 (0.26, 9.48)	0.6295	1.38 (0.51, 4.28)	0.6740	10.54 (-31.56, 52.65)	0.6235	
QMG >= 16	6 / 15 (40.0)	6 / 9 (66.7)	2.77 (0.44, 17.51)	0.2787	1.67 (0.74, 3.68)	0.4003	24.81 (-18.48, 68.10)	0.2613	
Baseline MGFA class									NA

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
II	3 / 12 (25.0)	9 / 13 (69.2)	NA	NA	NA	NA	NA	NA	
III	6 / 12 (50.0)	3 / 9 (33.3)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	5 / 15 (33.3)	9 / 14 (64.3)	NA	NA	NA	NA	NA	NA	
Europe	2 / 2 (100.0)	3 / 7 (42.9)	NA	NA	NA	NA	NA	NA	
North America	0 / 2 (0.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	2 / 5 (40.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	2 / 2 (100.0)	3 / 7 (42.9)	NA	NA	NA	NA	NA	NA	
Non-EU	7 / 22 (31.8)	10 / 17 (58.8)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	0 / 2 (0.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	9 / 22 (40.9)	12 / 22 (54.5)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects with assessment in each subgroup level. CI = Confidence interval. Baseline is defined as the last valid value on or prior to the 1st dose of Randomized controlled period. If a subject used rescue therapy between Day 28 and Week 52 or discontinued from the study before Week 52, the subject was considered as a non-responder.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.2.2 Anteil an Patientinnen und Patienten mit minimaler Symptomausprägung im MG-ADL (MG-ADL = 0 oder 1) (keine Rescue-Therapie)

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
AChR+ Population (Week 52)									
Age									0.4143
>= 18 - < 65 years	4 / 69 (5.8)	22 / 63 (34.9)	8.97 (2.94, 27.37)	0.0001	6.02 (2.34, 16.10)	<0.0001	27.07 (11.82, 42.32)	0.0005	
>= 65 years	1 / 10 (10.0)	4 / 16 (25.0)	2.82 (0.31, 25.34)	0.3541	2.50 (0.46, 15.74)	0.6169	13.74 (-12.77, 40.25)	0.3096	
Sex									0.6278
Male	3 / 39 (7.7)	8 / 27 (29.6)	3.50 (0.91, 13.56)	0.0693	3.85 (1.22, 12.53)	0.0400	17.15 (-3.62, 37.92)	0.1057	
Female	2 / 40 (5.0)	18 / 52 (34.6)	12.01 (2.71, 53.23)	0.0011	6.92 (1.97, 26.06)	0.0007	28.24 (11.91, 44.58)	0.0007	
Baseline steroid use									0.6173
Prednisone <= 20 mg/day	4 / 47 (8.5)	17 / 52 (32.7)	4.65 (1.49, 14.55)	0.0082	3.84 (1.49, 10.38)	0.0059	20.51 (5.17, 35.86)	0.0088	
Prednisone > 20 mg/day	1 / 27 (3.7)	8 / 24 (33.3)	9.76 (1.47, 64.66)	0.0182	9.00 (1.64, 53.62)	0.0085	35.03 (0.02, 70.04)	0.0499	
Baseline QMG									1.0000
QMG <= 15	2 / 31 (6.5)	12 / 29 (41.4)	7.51 (1.71, 32.98)	0.0076	6.41 (1.82, 24.38)	0.0019	32.05 (8.30, 55.80)	0.0082	
QMG >= 16	3 / 46 (6.5)	14 / 48 (29.2)	6.56 (1.73, 24.95)	0.0058	4.47 (1.51, 13.94)	0.0063	21.60 (6.76, 36.43)	0.0043	
Baseline MGFA class									0.7211
II	1 / 29 (3.4)	11 / 35 (31.4)	9.09 (1.57, 52.75)	0.0139	9.11 (1.69, 53.61)	0.0080	26.61 (8.09, 45.12)	0.0049	
III	4 / 42 (9.5)	14 / 41 (34.1)	5.19 (1.52, 17.76)	0.0087	3.59 (1.38, 9.78)	0.0080	23.74 (4.41, 43.08)	0.0161	
IV	0 / 7 (0.0)	1 / 3 (33.3)	ND	ND	6.00 (0.57, 65.88)	0.3000	ND	ND	
Region									0.3028
Asia	5 / 32 (15.6)	8 / 26 (30.8)	2.45 (0.68, 8.79)	0.1680	1.97 (0.76, 5.18)	0.2134	8.43 (-7.73, 24.59)	0.3064	

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
Europe	0 / 33 (0.0)	9 / 32 (28.1)	24.90 (1.74, 357.10)	0.0180	19.58 (2.14, 192.89)	0.0009	20.16 (-3.28, 43.59)	0.0918	
North America	0 / 11 (0.0)	5 / 14 (35.7)	23.24 (0.80, 675.10)	0.0672	8.80 (1.04, 87.81)	0.0464	38.65 (6.55, 70.74)	0.0183	
Rest of the world	0 / 3 (0.0)	4 / 7 (57.1)	ND	ND	4.50 (0.70, 44.25)	0.2000	ND	ND	
Region									0.2235
EU	0 / 33 (0.0)	9 / 32 (28.1)	24.90 (1.74, 357.10)	0.0180	19.58 (2.14, 192.89)	0.0009	20.16 (-3.28, 43.59)	0.0918	
Non-EU	5 / 46 (10.9)	17 / 47 (36.2)	4.68 (1.56, 14.04)	0.0058	3.33 (1.41, 8.19)	0.0065	23.09 (7.19, 38.99)	0.0044	
Region									NA
Japan	0 / 1 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	5 / 78 (6.4)	26 / 78 (33.3)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	3 / 22 (13.6)	3 / 21 (14.3)	NA	NA	NA	NA	NA	NA	
>= 65 years	0 / 2 (0.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	
Sex									NE
Male	2 / 7 (28.6)	0 / 5 (0.0)	NA	NA	NA	NA	NA	NA	
Female	1 / 17 (5.9)	3 / 19 (15.8)	NA	NA	NA	NA	NA	NA	
Baseline steroid use									NA
Prednisone <= 20 mg/day	2 / 13 (15.4)	2 / 19 (10.5)	NA	NA	NA	NA	NA	NA	
Prednisone > 20 mg/day	1 / 10 (10.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	
Baseline QMG									NA

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
QMG <= 15	2 / 9 (22.2)	1 / 13 (7.7)	NA	NA	NA	NA	NA	NA	
QMG >= 16	1 / 15 (6.7)	2 / 9 (22.2)	NA	NA	NA	NA	NA	NA	
Baseline MGFA class									NA
II	3 / 12 (25.0)	2 / 13 (15.4)	NA	NA	NA	NA	NA	NA	
III	0 / 12 (0.0)	1 / 9 (11.1)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	2 / 15 (13.3)	3 / 14 (21.4)	NA	NA	NA	NA	NA	NA	
Europe	1 / 2 (50.0)	0 / 7 (0.0)	NA	NA	NA	NA	NA	NA	
North America	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	0 / 5 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	1 / 2 (50.0)	0 / 7 (0.0)	NA	NA	NA	NA	NA	NA	
Non-EU	2 / 22 (9.1)	3 / 17 (17.6)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	3 / 22 (13.6)	3 / 22 (13.6)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects with assessment in each subgroup level. CI = Confidence interval.
Minimal symptom expression, defined as MG-ADL = 0 or 1.
If a subject used rescue therapy between Day 28 and Week 52 or discontinued from the study before Week 52, the subject was considered as a non-responder.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.									

1.3 Quantitativer Myasthenia gravis (QMG)

1.3.1 Anteil an Patientinnen und Patienten mit einer Verbesserung des QMG um ≥ 6 Punkte (keine Rescue-Therapie)

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
AChR+ Population (Week 52)									
Age									0.3050
>= 18 - < 65 years	12 / 67 (17.9)	35 / 61 (57.4)	5.95 (2.65, 13.39)	<0.0001	3.20 (1.88, 5.64)	<0.0001	40.30 (23.95, 56.66)	<0.0001	
>= 65 years	3 / 10 (30.0)	7 / 15 (46.7)	3.79 (0.39, 37.09)	0.2520	1.56 (0.58, 4.77)	0.6785	27.02 (-13.38, 67.42)	0.1899	
Sex									1.0000
Male	9 / 38 (23.7)	16 / 27 (59.3)	4.54 (1.49, 13.79)	0.0077	2.50 (1.34, 4.85)	0.0049	35.70 (11.31, 60.09)	0.0041	
Female	6 / 39 (15.4)	26 / 49 (53.1)	6.54 (2.25, 19.03)	0.0006	3.45 (1.68, 7.60)	0.0003	39.34 (20.40, 58.29)	<0.0001	
Baseline steroid use									0.6992
Prednisone <= 20 mg/day	9 / 46 (19.6)	30 / 51 (58.8)	5.44 (2.18, 13.59)	0.0003	3.01 (1.67, 5.72)	<0.0001	38.32 (19.87, 56.78)	<0.0001	
Prednisone > 20 mg/day	5 / 26 (19.2)	11 / 22 (50.0)	4.08 (1.00, 16.61)	0.0496	2.60 (1.12, 6.36)	0.0337	33.70 (2.04, 65.36)	0.0370	
Baseline QMG									1.0000
QMG <= 15	5 / 31 (16.1)	15 / 28 (53.6)	6.15 (1.75, 21.64)	0.0047	3.32 (1.48, 7.98)	0.0052	41.40 (15.73, 67.07)	0.0016	
QMG >= 16	10 / 46 (21.7)	27 / 48 (56.3)	4.51 (1.81, 11.25)	0.0012	2.59 (1.47, 4.79)	0.0007	33.59 (15.12, 52.07)	0.0004	
Baseline MGFA class									NA
II	6 / 29 (20.7)	20 / 34 (58.8)	NA	NA	NA	NA	NA	NA	
III	9 / 42 (21.4)	21 / 39 (53.8)	NA	NA	NA	NA	NA	NA	
IV	0 / 5 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	
Region									0.6805
Asia	9 / 32 (28.1)	14 / 25 (56.0)	3.51 (1.08, 11.35)	0.0364	1.99 (1.05, 3.87)	0.0560	28.17 (1.63, 54.71)	0.0375	
Europe	3 / 31 (9.7)	15 / 30 (50.0)	7.71 (1.99, 29.80)	0.0031	5.17 (1.85, 15.64)	0.0007	42.25 (16.27, 68.23)	0.0014	

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
North America	3 / 11 (27.3)	9 / 14 (64.3)	3.77 (0.69, 20.66)	0.1263	2.36 (0.95, 6.94)	0.1107	31.89 (-5.96, 69.74)	0.0987	
Rest of the world	0 / 3 (0.0)	4 / 7 (57.1)	ND	ND	4.50 (0.70, 44.25)	0.2000	ND	ND	
Region									0.4407
EU	3 / 31 (9.7)	15 / 30 (50.0)	7.71 (1.99, 29.80)	0.0031	5.17 (1.85, 15.64)	0.0007	42.25 (16.27, 68.23)	0.0014	
Non-EU	12 / 46 (26.1)	27 / 46 (58.7)	4.07 (1.64, 10.10)	0.0025	2.25 (1.34, 3.94)	0.0029	32.98 (13.36, 52.60)	0.0010	
Region									NA
Japan	0 / 1 (0.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	15 / 76 (19.7)	41 / 75 (54.7)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	6 / 22 (27.3)	9 / 20 (45.0)	NA	NA	NA	NA	NA	NA	
>= 65 years	0 / 2 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	
Sex									0.4970
Male	3 / 7 (42.9)	2 / 5 (40.0)	ND	ND	0.93 (0.23, 3.34)	1.0000	ND	ND	
Female	3 / 17 (17.6)	8 / 18 (44.4)	5.85 (0.87, 39.39)	0.0696	2.52 (0.88, 7.85)	0.1464	37.69 (1.17, 74.20)	0.0431	
Baseline steroid use									0.1522
Prednisone <= 20 mg/day	2 / 13 (15.4)	9 / 18 (50.0)	11.81 (1.18, 118.24)	0.0356	3.25 (1.01, 12.25)	0.0656	51.17 (12.96, 89.37)	0.0087	
Prednisone > 20 mg/day	3 / 10 (30.0)	0 / 2 (0.0)	3.44 (0.02, 743.98)	0.6522	0.52 (0.05, 3.40)	1.0000	26.00 (-95.01, 147.00)	0.6737	
Baseline QMG									0.9184
QMG <= 15	0 / 9 (0.0)	3 / 13 (23.1)	6.22 (0.23, 165.28)	0.2747	5.00 (0.56, 51.72)	0.2403	21.85 (-10.02, 53.71)	0.1790	

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
QMG >= 16	6 / 15 (40.0)	7 / 9 (77.8)	3.76 (0.58, 24.58)	0.1664	1.94 (0.94, 4.13)	0.1049	29.02 (-8.50, 66.54)	0.1295	
Baseline MGFA class									NA
II	1 / 12 (8.3)	7 / 13 (53.8)	NA	NA	NA	NA	NA	NA	
III	5 / 12 (41.7)	3 / 9 (33.3)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	0 / 0 (-)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	1 / 15 (6.7)	8 / 14 (57.1)	NA	NA	NA	NA	NA	NA	
Europe	1 / 2 (50.0)	1 / 6 (16.7)	NA	NA	NA	NA	NA	NA	
North America	1 / 2 (50.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	3 / 5 (60.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	1 / 2 (50.0)	1 / 6 (16.7)	NA	NA	NA	NA	NA	NA	
Non-EU	5 / 22 (22.7)	9 / 17 (52.9)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	0 / 2 (0.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	6 / 22 (27.3)	8 / 21 (38.1)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects with assessment in each subgroup level. CI = Confidence interval.
Baseline is defined as the last valid value on or prior to the 1st dose of Randomized controlled period.
If a subject used rescue therapy between Day 28 and Week 26 or discontinued from the study before Week 26, the subject was considered as a non-responder.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score, and baseline MG-ADL score as common covariates. 95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.4 Myasthenia gravis Composite (MGC)

1.4.1 Anteil an Patientinnen und Patienten mit Verbesserung des MGC um ≥ 8 Punkte (keine Rescue-Therapie)

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	21 / 69 (30.4)	36 / 63 (57.1)	3.47 (1.64, 7.35)	0.0012	1.88 (1.25, 2.87)	0.0027	29.92 (12.88, 46.96)	0.0006	
>= 65 years	2 / 10 (20.0)	6 / 15 (40.0)	2.99 (0.25, 35.25)	0.3840	2.00 (0.60, 7.80)	0.4018	16.36 (-17.84, 50.56)	0.3484	
Sex									0.0179
Male	16 / 39 (41.0)	12 / 27 (44.4)	0.91 (0.31, 2.67)	0.8612	1.08 (0.60, 1.88)	0.8051	-2.35 (-28.62, 23.92)	0.8609	
Female	7 / 40 (17.5)	30 / 51 (58.8)	9.15 (3.00, 27.90)	<0.0001	3.36 (1.74, 6.94)	<0.0001	46.82 (27.35, 66.29)	<0.0001	
Baseline steroid use									1.0000
Prednisone <= 20 mg/day	16 / 47 (34.0)	29 / 52 (55.8)	2.41 (1.05, 5.55)	0.0391	1.64 (1.05, 2.65)	0.0430	21.55 (1.73, 41.38)	0.0331	
Prednisone > 20 mg/day	7 / 27 (25.9)	12 / 23 (52.2)	3.37 (0.93, 12.25)	0.0646	2.01 (0.98, 4.30)	0.0812	28.95 (0.28, 57.62)	0.0478	
Baseline QMG									0.2981
QMG <= 15	12 / 31 (38.7)	14 / 28 (50.0)	1.62 (0.55, 4.77)	0.3832	1.29 (0.73, 2.32)	0.4383	11.89 (-14.65, 38.42)	0.3800	
QMG >= 16	11 / 46 (23.9)	26 / 48 (54.2)	4.59 (1.77, 11.91)	0.0018	2.27 (1.31, 4.09)	0.0033	34.23 (14.53, 53.93)	0.0007	
Baseline MGFA class									NA
II	9 / 29 (31.0)	15 / 34 (44.1)	1.84 (0.61, 5.55)	0.2782	1.42 (0.75, 2.80)	0.3115	14.88 (-11.58, 41.34)	0.2703	
III	13 / 42 (31.0)	27 / 41 (65.9)	3.73 (1.46, 9.56)	0.0061	2.13 (1.32, 3.59)	0.0021	31.66 (10.56, 52.76)	0.0033	
IV	0 / 7 (0.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	
Region									0.0029
Asia	14 / 32 (43.8)	13 / 25 (52.0)	1.23 (0.42, 3.60)	0.7030	1.19 (0.68, 2.05)	0.5994	5.19 (-21.46, 31.84)	0.7029	

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
Europe	3 / 33 (9.1)	19 / 32 (59.4)	14.52 (3.44, 61.23)	0.0003	6.53 (2.39, 19.47)	<0.0001	54.04 (29.16, 78.92)	<0.0001	
North America	6 / 11 (54.5)	5 / 14 (35.7)	0.72 (0.11, 4.93)	0.7388	0.65 (0.27, 1.58)	0.4347	-8.13 (-55.75, 39.48)	0.7378	
Rest of the world	0 / 3 (0.0)	5 / 7 (71.4)	ND	ND	5.50 (0.93, 53.27)	0.1667	ND	ND	
Region									0.0046
EU	3 / 33 (9.1)	19 / 32 (59.4)	14.52 (3.44, 61.23)	0.0003	6.53 (2.39, 19.47)	<0.0001	54.04 (29.16, 78.92)	<0.0001	
Non-EU	20 / 46 (43.5)	23 / 46 (50.0)	1.42 (0.60, 3.39)	0.4257	1.15 (0.74, 1.80)	0.6763	8.78 (-12.71, 30.28)	0.4233	
Region									NA
Japan	0 / 1 (0.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	23 / 78 (29.5)	41 / 77 (53.2)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	11 / 22 (50.0)	13 / 21 (61.9)	NA	NA	NA	NA	NA	NA	
>= 65 years	0 / 2 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	
Sex									0.4937
Male	4 / 7 (57.1)	2 / 5 (40.0)	ND	ND	0.70 (0.19, 2.17)	1.0000	ND	ND	
Female	7 / 17 (41.2)	12 / 19 (63.2)	2.34 (0.56, 9.76)	0.2450	1.53 (0.82, 3.11)	0.3161	20.71 (-13.32, 54.75)	0.2329	
Baseline steroid use									1.0000
Prednisone <= 20 mg/day	5 / 13 (38.5)	11 / 19 (57.9)	2.80 (0.57, 13.79)	0.2065	1.51 (0.73, 3.50)	0.4725	25.14 (-12.26, 62.55)	0.1876	
Prednisone > 20 mg/day	5 / 10 (50.0)	1 / 2 (50.0)	2.22 (0.07, 68.07)	0.6488	1.00 (0.18, 2.97)	1.0000	18.84 (-56.26, 93.94)	0.6230	
Baseline QMG									1.0000

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
QMG <= 15	3 / 9 (33.3)	6 / 13 (46.2)	3.15 (0.37, 27.18)	0.2967	1.38 (0.51, 4.28)	0.6740	27.40 (-20.81, 75.61)	0.2654	
QMG >= 16	8 / 15 (53.3)	7 / 9 (77.8)	2.29 (0.36, 14.73)	0.3825	1.46 (0.76, 2.74)	0.3891	18.01 (-20.81, 56.82)	0.3632	
Baseline MGFA class									NA
II	3 / 12 (25.0)	9 / 13 (69.2)	NA	NA	NA	NA	NA	NA	
III	8 / 12 (66.7)	4 / 9 (44.4)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	5 / 15 (33.3)	10 / 14 (71.4)	NA	NA	NA	NA	NA	NA	
Europe	2 / 2 (100.0)	3 / 7 (42.9)	NA	NA	NA	NA	NA	NA	
North America	1 / 2 (50.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	3 / 5 (60.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	2 / 2 (100.0)	3 / 7 (42.9)	NA	NA	NA	NA	NA	NA	
Non-EU	9 / 22 (40.9)	11 / 17 (64.7)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	0 / 2 (0.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	11 / 22 (50.0)	12 / 22 (54.5)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MGC = Myasthenia Gravis Composite. MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects with assessment in each subgroup level. CI = Confidence interval.
Baseline is defined as the last valid value on or prior to the 1st dose of Randomized controlled period.
If a subject used rescue therapy between Day 28 and Week 26 or discontinued from the study before Week 26, the subject was considered as a non-responder.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), baseline MG-ADL score, and baseline MGC score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.									

1.5 Exazerbationen und myasthene Krisen

1.5.1 Anteil an Patientinnen und Patienten mit Exazerbationen (Treatment-policy Strategie)

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	36 / 79 (45.6)	16 / 76 (21.1)	0.33 (0.16, 0.67)	0.0020	0.46 (0.28, 0.75)	0.0013	-22.83 (-36.83, -8.83)	0.0014	
>= 65 years	5 / 14 (35.7)	3 / 19 (15.8)	0.50 (0.10, 2.61)	0.4092	0.44 (0.13, 1.44)	0.2379	-11.17 (-39.08, 16.74)	0.4328	
Sex									1.0000
Male	18 / 45 (40.0)	5 / 35 (14.3)	0.29 (0.10, 0.90)	0.0313	0.36 (0.15, 0.81)	0.0137	-22.28 (-41.34, -3.23)	0.0219	
Female	23 / 48 (47.9)	14 / 60 (23.3)	0.34 (0.15, 0.79)	0.0123	0.49 (0.28, 0.83)	0.0087	-22.61 (-40.32, -4.90)	0.0123	
Baseline steroid use									1.0000
Prednisone <= 20 mg/day	20 / 54 (37.0)	9 / 63 (14.3)	0.31 (0.13, 0.75)	0.0096	0.39 (0.19, 0.76)	0.0054	-22.28 (-39.01, -5.54)	0.0091	
Prednisone > 20 mg/day	18 / 30 (60.0)	9 / 27 (33.3)	0.36 (0.12, 1.13)	0.0794	0.56 (0.29, 0.99)	0.0637	-21.15 (-50.01, 7.70)	0.1508	
Baseline QMG									1.0000
QMG <= 15	15 / 39 (38.5)	6 / 38 (15.8)	0.30 (0.10, 0.91)	0.0339	0.41 (0.18, 0.90)	0.0397	-23.78 (-44.45, -3.11)	0.0241	
QMG >= 16	25 / 52 (48.1)	12 / 55 (21.8)	0.31 (0.13, 0.73)	0.0074	0.45 (0.25, 0.79)	0.0049	-23.43 (-40.31, -6.56)	0.0065	
Baseline MGFA class									0.3263
II	16 / 36 (44.4)	6 / 43 (14.0)	0.25 (0.09, 0.74)	0.0120	0.31 (0.14, 0.69)	0.0049	-24.52 (-44.53, -4.50)	0.0164	
III	19 / 49 (38.8)	12 / 49 (24.5)	0.51 (0.21, 1.23)	0.1368	0.63 (0.34, 1.14)	0.1921	-13.61 (-31.22, 4.00)	0.1297	
IV	6 / 7 (85.7)	1 / 3 (33.3)	ND	ND	0.39 (0.07, 1.15)	0.1833	ND	ND	
Region									0.5605
Asia	13 / 39 (33.3)	6 / 30 (20.0)	0.47 (0.15, 1.49)	0.2010	0.60 (0.26, 1.33)	0.2815	-11.06 (-28.34, 6.23)	0.2099	
Europe	19 / 39 (48.7)	6 / 37 (16.2)	0.22 (0.07, 0.64)	0.0054	0.33 (0.15, 0.70)	0.0034	-30.41 (-49.98, -10.85)	0.0023	

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
North America	6 / 12 (50.0)	4 / 19 (21.1)	0.32 (0.07, 1.56)	0.1589	0.42 (0.15, 1.15)	0.1271	-25.74 (-60.60, 9.13)	0.1479	
Rest of the world	3 / 3 (100.0)	3 / 9 (33.3)	0.27 (0.00, 14.65)	0.5205	0.40 (0.15, 1.12)	0.1818	-30.53 (-111.37, 50.31)	0.4592	
Region									0.3334
EU	19 / 39 (48.7)	6 / 37 (16.2)	0.22 (0.07, 0.64)	0.0054	0.33 (0.15, 0.70)	0.0034	-30.41 (-49.98, -10.85)	0.0023	
Non-EU	22 / 54 (40.7)	13 / 58 (22.4)	0.44 (0.19, 1.01)	0.0530	0.55 (0.31, 0.96)	0.0430	-16.12 (-32.48, 0.24)	0.0535	
Region									NA
Japan	1 / 1 (100.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	40 / 92 (43.5)	19 / 94 (20.2)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	9 / 22 (40.9)	3 / 21 (14.3)	NA	NA	NA	NA	NA	NA	
>= 65 years	2 / 2 (100.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	
Sex									NA
Male	4 / 7 (57.1)	1 / 5 (20.0)	NA	NA	NA	NA	NA	NA	
Female	7 / 17 (41.2)	2 / 19 (10.5)	NA	NA	NA	NA	NA	NA	
Baseline steroid use									NA
Prednisone <= 20 mg/day	4 / 13 (30.8)	3 / 19 (15.8)	NA	NA	NA	NA	NA	NA	
Prednisone > 20 mg/day	6 / 10 (60.0	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	
Baseline QMG									NA
QMG <= 15	4 / 9 (44.4)	1 / 13 (7.7)	NA	NA	NA	NA	NA	NA	
QMG >= 16	7 / 15 (46.7)	1 / 9 (11.1)	NA	NA	NA	NA	NA	NA	
Baseline MGFA class									NA
II	7 / 12 (58.3)	1 / 13 (7.7)	NA	NA	NA	NA	NA	NA	
III	4 / 12 (33.3)	2 / 9 (22.2)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
Region									NA
Asia	6 / 15 (40.0)	1 / 14 (7.1)	NA	NA	NA	NA	NA	NA	
Europe	1 / 2 (50.0)	2 / 7 (28.6)	NA	NA	NA	NA	NA	NA	
North America	1 / 2 (50.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	3 / 5 (60.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	1 / 2 (50.0)	2 / 7 (28.6)	NA	NA	NA	NA	NA	NA	
Non-EU	10 / 22 (45.5)	1 / 17 (5.9)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	1 / 2 (50.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	10 / 22 (45.5)	3 / 22 (13.6)	NA	NA	NA	NA	NA	NA	

An exacerbation is defined as Use of protocol defined rescue therapy, or Myasthenic crisis or Significant symptomatic worsening.
MG crisis is defined as worsening of myasthenic weakness requiring intubation or noninvasive ventilation to avoid intubation, except when these measures are employed during routine postoperative management.
Significant symptomatic worsening is defined as MG-ADL total score of 3 or a 2-point worsening from baseline on any one of the individual items other than double vision or eyelid droop.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects in each subgroup level. CI = Confidence interval.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.5.2 Zeit bis zur ersten Exazerbation (Treatment-policy Strategie)

Subgroup	Placebo	Inebilizumab
AChR+ Population (Week 52)		
Treatment by age interaction p-value[a]		0.9244
Age		
>= 18 - < 65 years		
Subjects with exacerbation - n / N1 (%)	36 / 79 (45.6)	16 / 76 (21.1)
Median time to first exacerbation (months)b	NA	NA
95% CI[b]	8.77, NA	NA, NA
Hazard ratio[c]	0.42	
95% CI[c]	0.23, 0.75	
p-value[c]	0.0035	
>= 65 years		
Subjects with exacerbation - n / N1 (%)	5 / 14 (35.7)	3 / 19 (15.8)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	1.94, NA	NA, NA
Hazard ratio[c]	0.42	
95% CI[c]	0.09, 1.89	
p-value[c]	0.2587	
Treatment by sex interaction p-value[a]		0.8159
Sex		
Male		
Subjects with exacerbation - n / N1 (%)	18 / 45 (40.0)	5 / 35 (14.3)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	7.75, NA	NA, NA
Hazard ratio[c]	0.34	
95% CI[c]	0.12, 0.95	
p-value[c]	0.0388	
Female		
Subjects with exacerbation - n / N1 (%)	23 / 48 (47.9)	14 / 60 (23.3)
Median time to first exacerbation (months)[b]	11.37	NA
95% CI[b]	5.98, NA	NA, NA
Hazard ratio[c]	0.41	
95% CI[c]	0.21, 0.82	
p-value[c]	0.0110	
Treatment by baseline steroid use interaction p-value[a]		0.6323

Subgroup	Placebo	Inebilizumab
Baseline steroid use		
Prednisone <= 20 mg/day		
Subjects with exacerbation - n / N1 (%)	20 / 54 (37.0)	9 / 63 (14.3)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	8.77, NA	NA, NA
Hazard ratio[c]	0.36	
95% CI[c]	0.16, 0.80	
p-value[c]	0.0115	
Prednisone > 20 mg/day		
Subjects with exacerbation - n / N1 (%)	18 / 30 (60.0)	9 / 27 (33.3)
Median time to first exacerbation (months)[b]	10.45	NA
95% CI[b]	6.01, NA	7.43, NA
Hazard ratio[c]	0.50	
95% CI[c]	0.22, 1.12	
p-value[c]	0.0935	
Treatment by baseline QMG interaction p-value[a]		0.8812
Baseline QMG		
QMG <= 15		
Subjects with exacerbation - n / N1 (%)	15 / 39 (38.5)	6 / 38 (15.8)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	8.77, NA	NA, NA
Hazard ratioc	0.37	
95% CI[c]	0.14, 0.98	
p-value[c]	0.0445	
QMG >= 16		
Subjects with exacerbation - n / N1 (%)	25 / 52 (48.1)	12 / 55 (21.8)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	7.43, NA	NA, NA
Hazard ratio[c]	0.38	
95% CI[c]	0.19, 0.76	
p-value[c]	0.0061	
Treatment by baseline MGFA class interaction p-value[a]		0.5669
Baseline MGFA class		
II		

Subgroup	Placebo	Inebilizumab
Subjects with exacerbation - n / N1 (%)	16 / 36 (44.4)	6 / 43 (14.0)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	7.79, NA	NA, NA
Hazard ratio[c]	0.32	
95% CI[c]	0.12, 0.83	
p-value[c]	0.0186	
III		
Subjects with exacerbation - n / N1 (%)	19 / 49 (38.8)	12 / 49 (24.5)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	7.43, NA	NA, NA
Hazard ratio[c]	0.54	
95% CI[c]	0.26, 1.11	
p-value[c]	0.0921	
IV		
Subjects with exacerbation - n / N1 (%)	6 / 7 (85.7)	1 / 3 (33.3)
Median time to first exacerbation (months)[b]	3.55	NA
95% CI[b]	0.49, 7.46	1.22, NA
Hazard ratio[c]	0.48	
95% CI[c]	0.03, 7.88	
p-value[c]	0.6081	
Treatment by region interaction p-value[a]		0.8544
Region		
Asia		
Subjects with exacerbation - n / N1 (%)	13 / 39 (33.3)	6 / 30 (20.0)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	11.33, NA	NA, NA
Hazard ratio[c]	0.43	
95% CI[c]	0.16, 1.16	
p-value[c]	0.0968	
Europe		
Subjects with exacerbation - n / N1 (%)	19 / 39 (48.7)	6 / 37 (16.2)
Median time to first exacerbation (months)[b]	11.07	NA
95% CI[b]	5.78, NA	NA, NA
Hazard ratio[c]	0.28	
95% CI[c]	0.11, 0.72	

Subgroup	Placebo	Inebilizumab
p-value[c]	0.0079	
North America		
Subjects with exacerbation - n / N1 (%)	6 / 12 (50.0)	4 / 19 (21.1)
Median time to first exacerbation (months)[b]	10.32	NA
95% CI[b]	2.40, NA	NA, NA
Hazard ratio[c]	0.39	
95% CI[c]	0.11, 1.43	
p-value[c]	0.1564	
Rest of the world		
Subjects with exacerbation - n / N1 (%)	3 / 3 (100.0)	3 / 9 (33.3)
Median time to first exacerbation (months)[b]	5.52	NA
95% CI[b]	1.58, NA	1.22, NA
Hazard ratio[c]	0.62	
95% CI[c]	0.10, 3.99	
p-value[c]	0.6155	
Treatment by region interaction p-value[a]		0.3118
Region		
EU		
Subjects with exacerbation - n / N1 (%)	19 / 39 (48.7)	6 / 37 (16.2)
Median time to first exacerbation (months)[b]	11.07	NA
95% CI[b]	5.78, NA	NA, NA
Hazard ratio[c]	0.28	
95% CI[c]	0.11, 0.72	
p-value[c]	0.0079	
Non-EU		
Subjects with exacerbation - n / N1 (%)	22 / 54 (40.7)	13 / 58 (22.4)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	10.32, NA	NA, NA
Hazard ratio[c]	0.51	
95% CI[c]	0.25, 1.01	
p-value[c]	0.0532	
Treatment by region interaction p-value[a]		NA
Region		
Japan		

Subgroup	Placebo	Inebilizumab
Subjects with exacerbation - n / N1 (%)	1 / 1 (100.0)	0 / 1 (0.0)
Median time to first exacerbation (months)[b]	1.91	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Non-Japan		
Subjects with exacerbation - n / N1 (%)	40 / 92 (43.5)	19 / 94 (20.2)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	8.77, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
MuSK+ Population (Week 26)		
Treatment by age interaction p-value[a]		NA
Age		
>= 18 - < 65 years		
Subjects with exacerbation - n / N1 (%)	9 / 22 (40.9)	3 / 21 (14.3)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	2.69, NA	6.44, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
>= 65 years		
Subjects with exacerbation - n / N1 (%)	2 / 2 (100.0)	0 / 3 (0.0)
Median time to first exacerbation (months)[b]	4.48	NA
95% CI[b]	4.11, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by sex interaction p-value[a]		NA
Sex		
Male		
Subjects with exacerbation - n / N1 (%)	4 / 7 (57.1)	1 / 5 (20.0)

Subgroup	Placebo	Inebilizumab
Median time to first exacerbation (months)[b]	4.86	NA
95% CI[b]	0.49, NA	6.44, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Female		
Subjects with exacerbation - n / N1 (%)	7 / 17 (41.2)	2 / 19 (10.5)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	2.69, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by baseline steroid use interaction p-value[a]		NA
Baseline steroid use		
Prednisone <= 20 mg/day		
Subjects with exacerbation - n / N1 (%)	4 / 13 (30.8)	3 / 19 (15.8)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	2.79, NA	6.44, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Prednisone > 20 mg/day		
Subjects with exacerbation - n / N1 (%)	6 / 10 (60.0)	0 / 2 (0.0)
Median time to first exacerbation (months)[b]	4.48	NA
95% CI[b]	0.46, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by baseline QMG interaction p-value[a]		NA
Baseline QMG		
QMG <= 15		
Subjects with exacerbation - n / N1 (%)	4 / 9 (44.4)	1 / 13 (7.7)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	0.99, NA	6.44, NA

Subgroup	Placebo	Inebilizumab
Hazard ratioc	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
QMG >= 16		
Subjects with exacerbation - n / N1 (%)	7 / 15 (46.7)	1 / 9 (11.1)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	0.49, NA	0.95, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by baseline MGFA class interaction p-value[a]		NA
Baseline MGFA class		
II		
Subjects with exacerbation - n / N1 (%)	7 / 12 (58.3)	1 / 13 (7.7)
Median time to first exacerbation (months)[b]	4.34	NA
95% CI[b]	0.99, NA	6.44, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
III		
Subjects with exacerbation - n / N1 (%)	4 / 12 (33.3)	2 / 9 (22.2)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	0.49, NA	0.95, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
IV		
Subjects with exacerbation - n / N1 (%)	0 / 0 (-)	0 / 1 (0.0)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by region interaction p-value[a]		NA

Subgroup	Placebo	Inebilizumab
Region		
Asia		
Subjects with exacerbation - n / N1 (%)	6 / 15 (40.0)	1 / 14 (7.1)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	2.79, NA	6.44, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Europe		
Subjects with exacerbation - n / N1 (%)	1 / 2 (50.0)	2 / 7 (28.6)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	0.46, NA	0.95, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
North America		
Subjects with exacerbation - n / N1 (%)	1 / 2 (50.0)	0 / 2 (0.0)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	2.69, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Rest of the world		
Subjects with exacerbation - n / N1 (%)	3 / 5 (60.0)	0 / 1 (0.0)
Median time to first exacerbation (months)[b]	4.11	NA
95% CI[b]	0.49, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by region interaction p-value[a]		NA
Region		
EU		
Subjects with exacerbation - n / N1 (%)	1 / 2 (50.0)	2 / 7 (28.6)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	0.46, NA	0.95, NA

Subgroup	Placebo	Inebilizumab
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Non-EU		
Subjects with exacerbation - n / N1 (%)	10 / 22 (45.5)	1 / 17 (5.9)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	2.79, NA	6.44, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by region interaction p-value[a]		NA
Region		
Japan		
Subjects with exacerbation - n / N1 (%)	1 / 2 (50.0)	0 / 2 (0.0)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	2.79, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Non-Japan		
Subjects with exacerbation - n / N1 (%)	10 / 22 (45.5)	3 / 22 (13.6)
Median time to first exacerbation (months)[b]	NA	NA
95% CI[b]	2.69, NA	6.44, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	

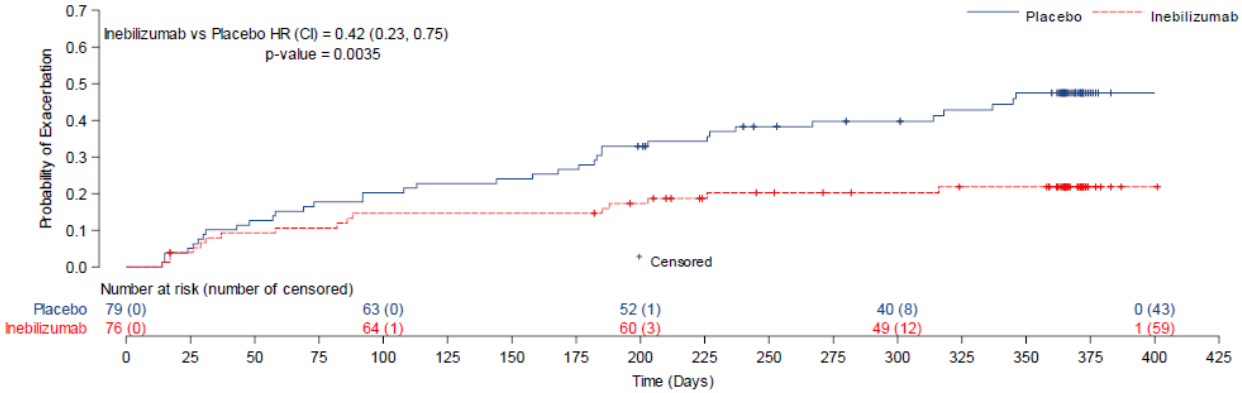
Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects in each subgroup level. CI = Confidence interval.
To convert days to months: 1 month = 30.4375 days. An exacerbation is defined as Use of protocol defined rescue therapy, or Myasthenic crisis or Significant symptomatic worsening.
[a] Based on Cox regression method, with common covariates of treatment group, baseline steroid use status (daily prednisone dose <= 5 mg vs daily prednisone dose > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), baseline MG-ADL score, subgroup variable, and treatment × subgroup variable.
[b] Based on Kaplan-Meier method.

Subgroup	Placebo	Inebilizumab
[c] Based on Cox regression method, with common covariates of treatment group, baseline steroid use status (daily prednisone dose <= 5 mg vs daily prednisone dose > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score.		

1.5.3 Kaplan-Meier-Kurven: Zeit bis zur ersten Exazerbation (Treatment-policy Strategie)

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

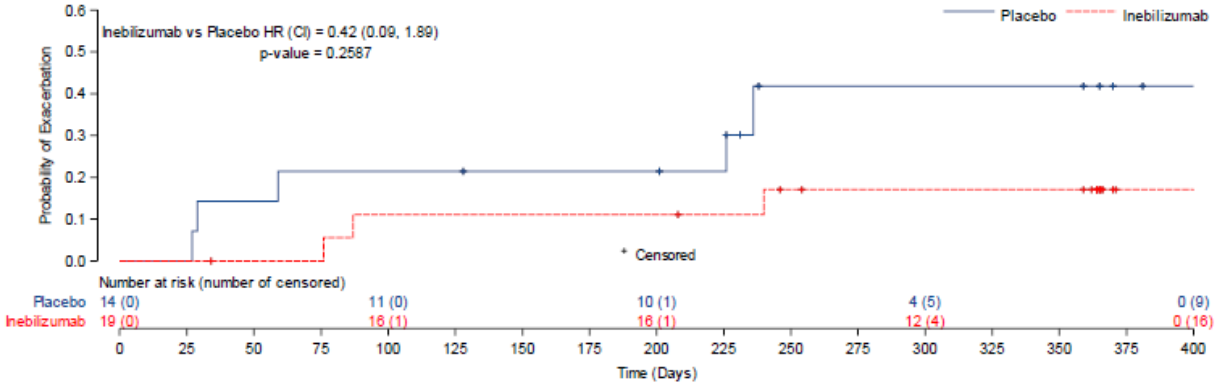
Subgroup = Age >= 18 - < 65 years



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

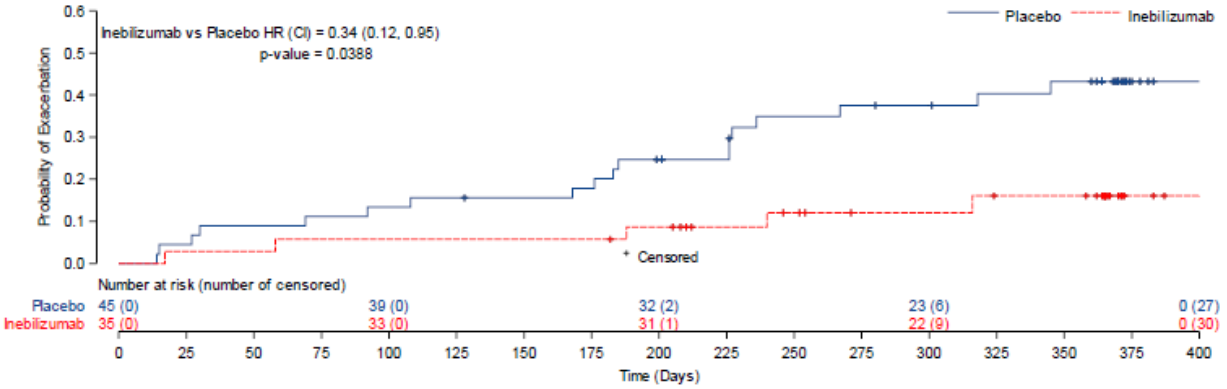
Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

Subgroup = Age >= 65 years



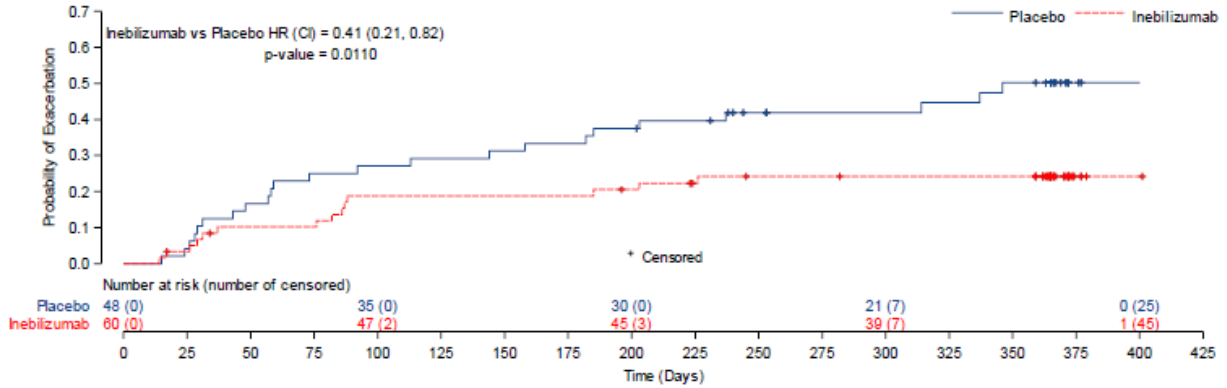
Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

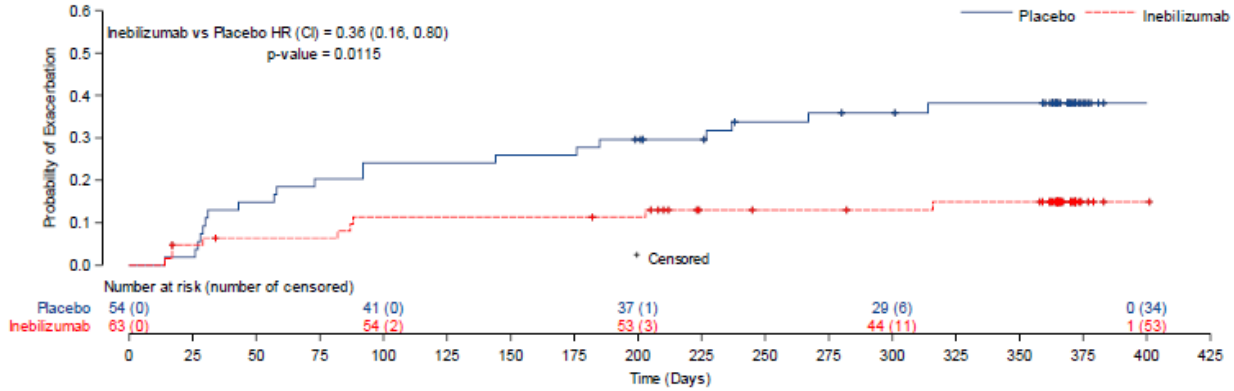
Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

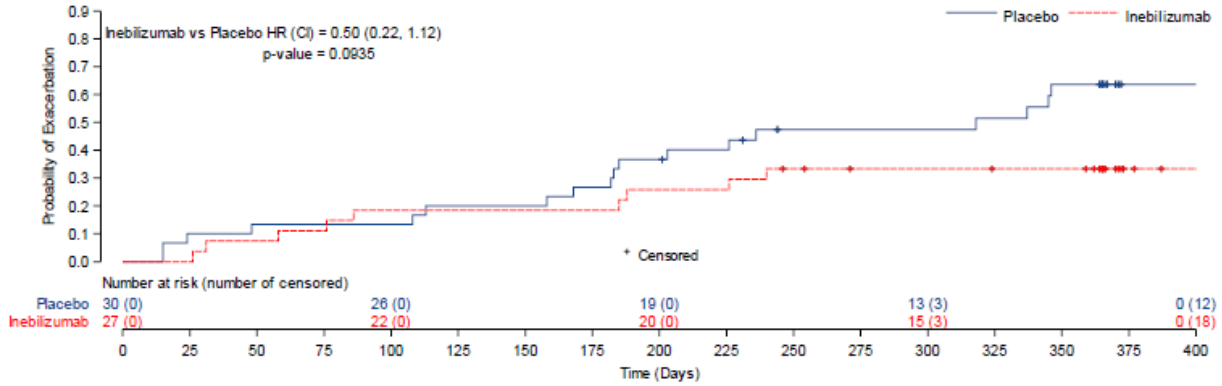
Subgroup = Baseline steroid use Prednisone <= 20 mg/day



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

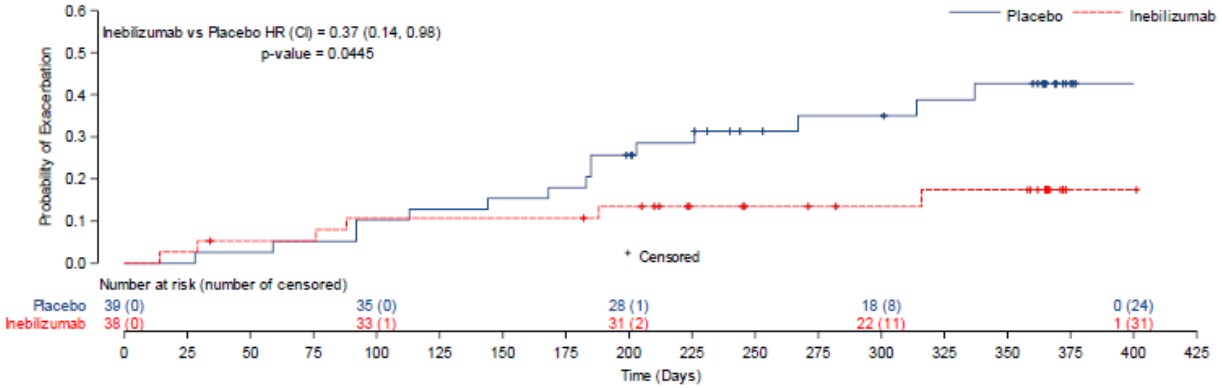
Subgroup = Baseline steroid use Prednisone > 20 mg/day



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

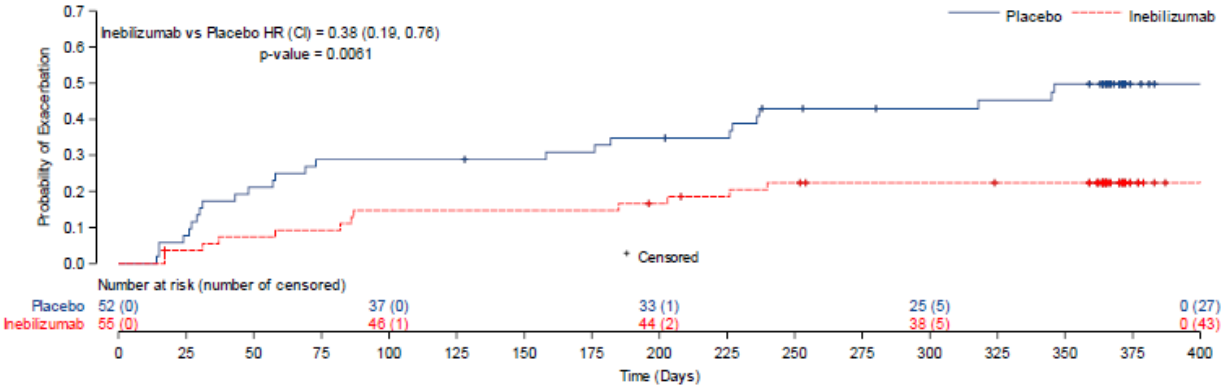
Subgroup = Baseline QMG QMG <= 15



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

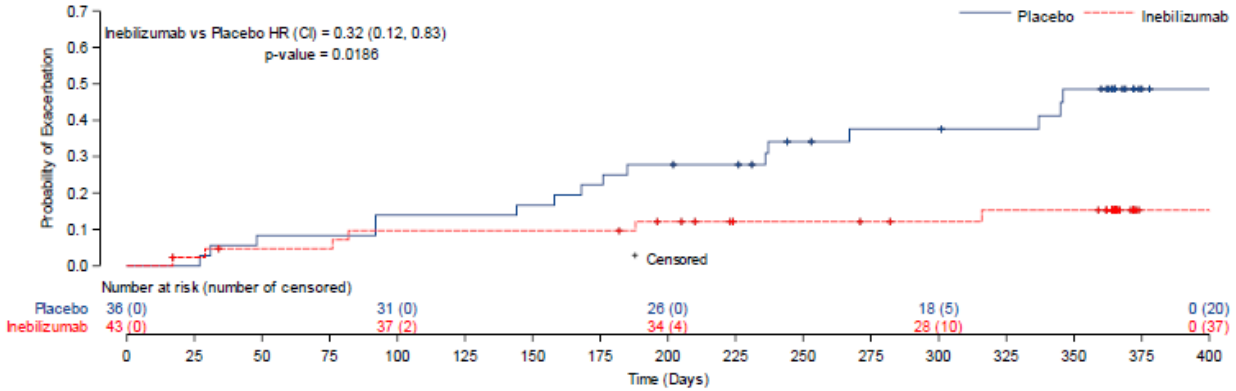
Subgroup = Baseline QMG QMG >= 16



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

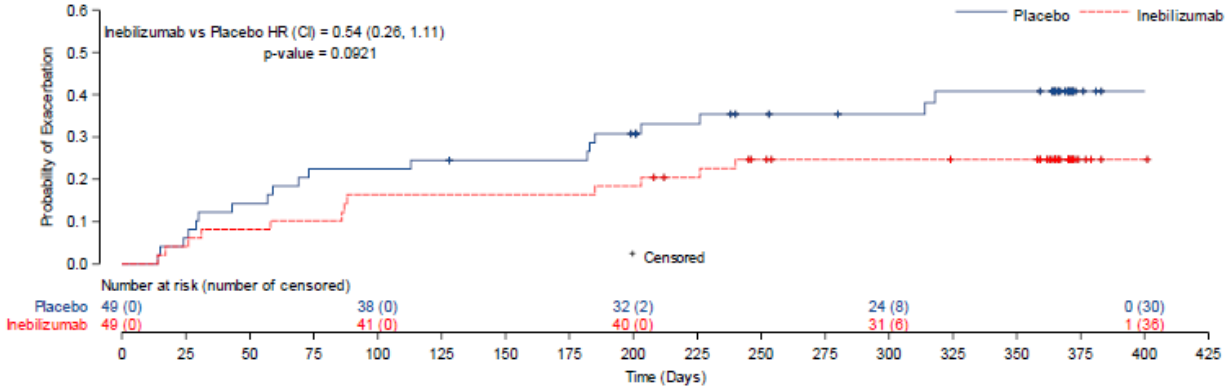
Subgroup = Baseline MGFA class II



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

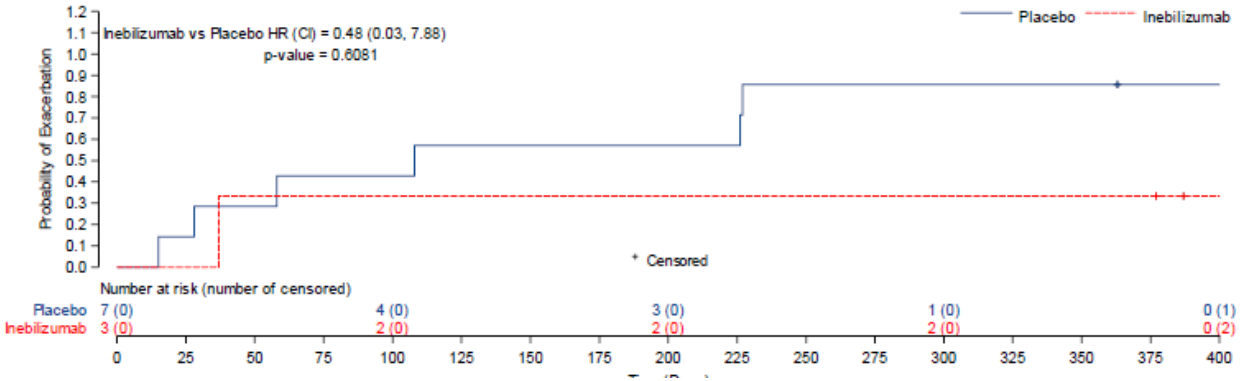
Subgroup = Baseline MGFA class III



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

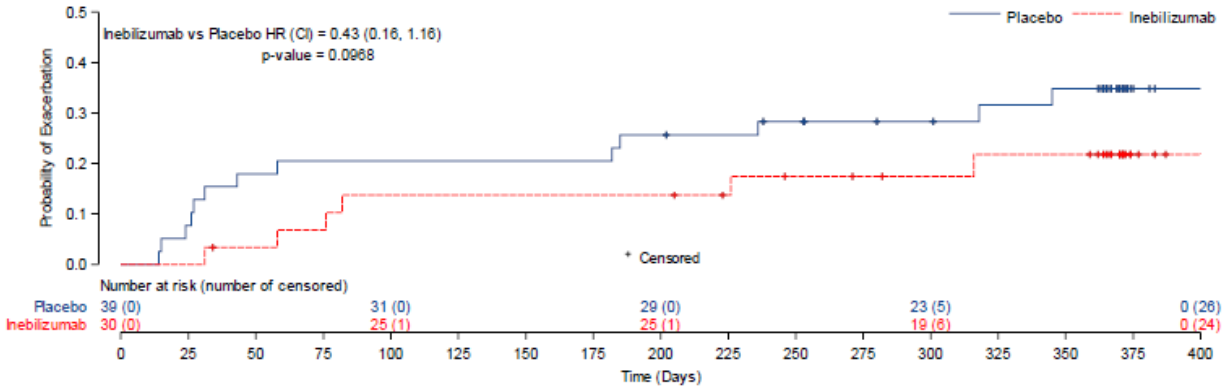
Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

Subgroup = Baseline MGFA class IV



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

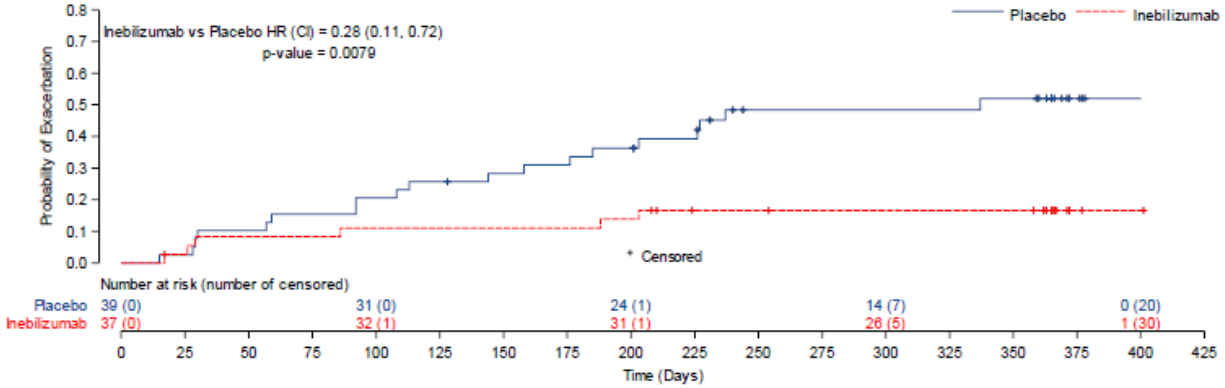
Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

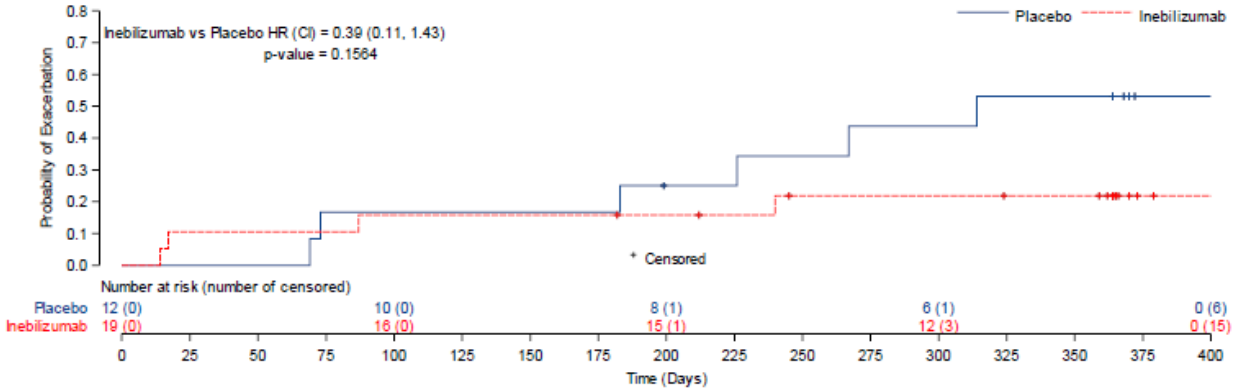
Subgroup = Region Europe



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

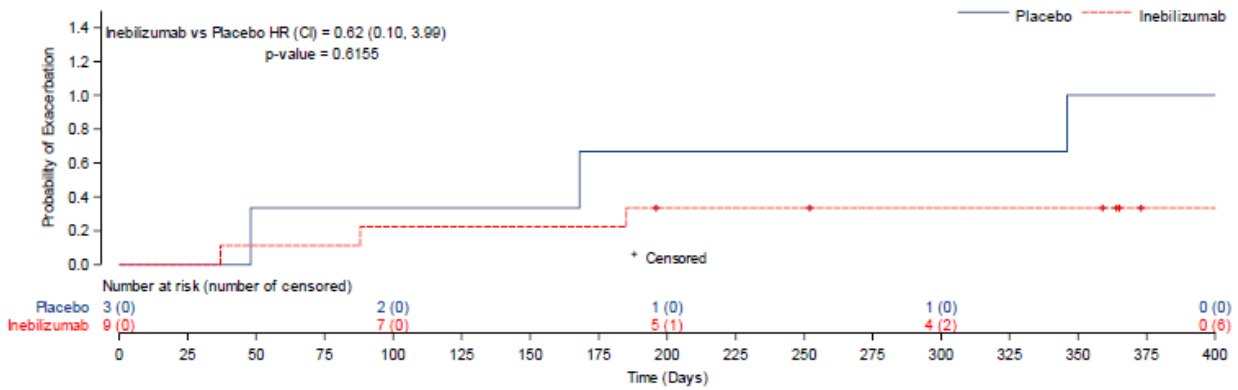
Subgroup = Region North America



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

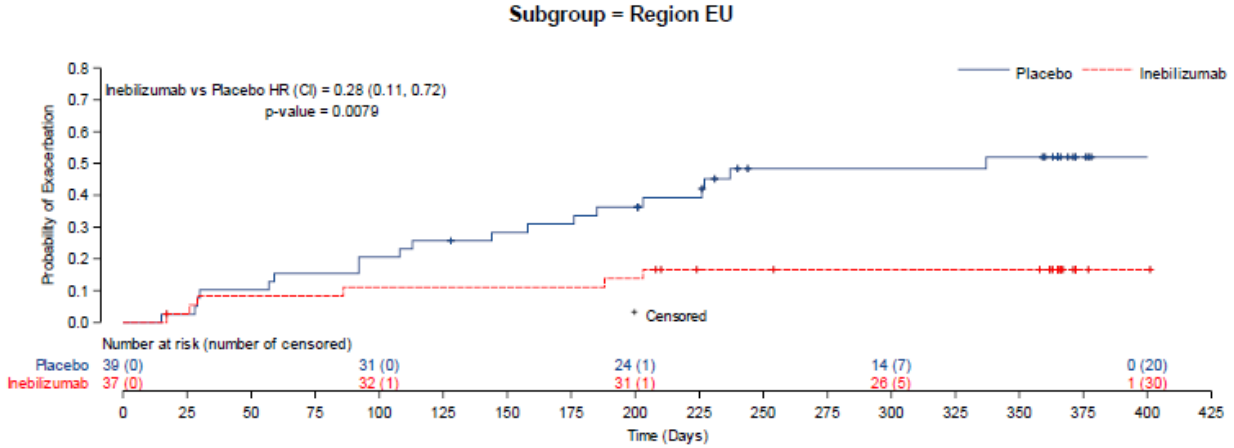
Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

Subgroup = Region Rest of the world



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

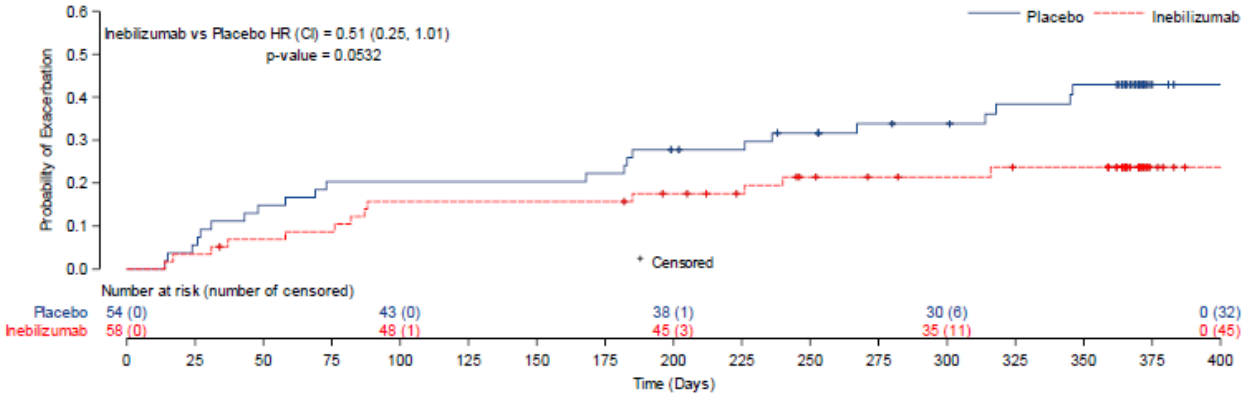
Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

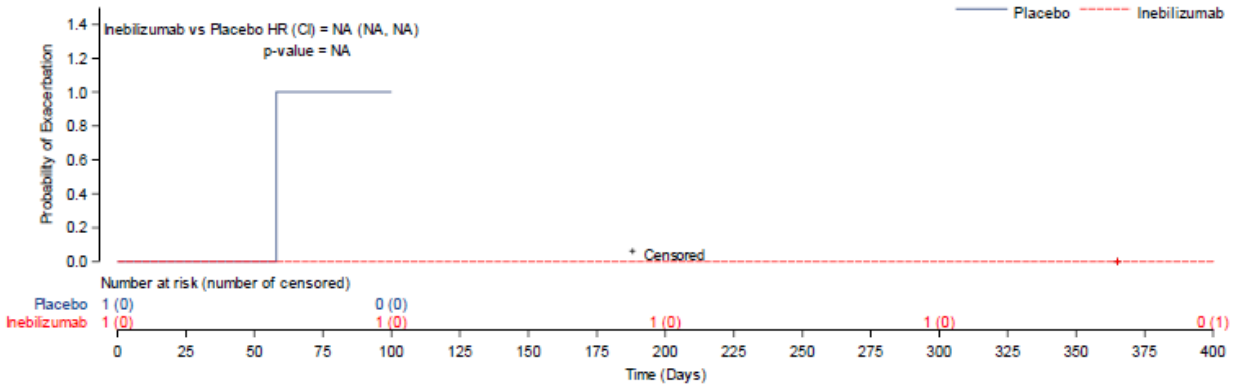
Subgroup = Region Non-EU



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

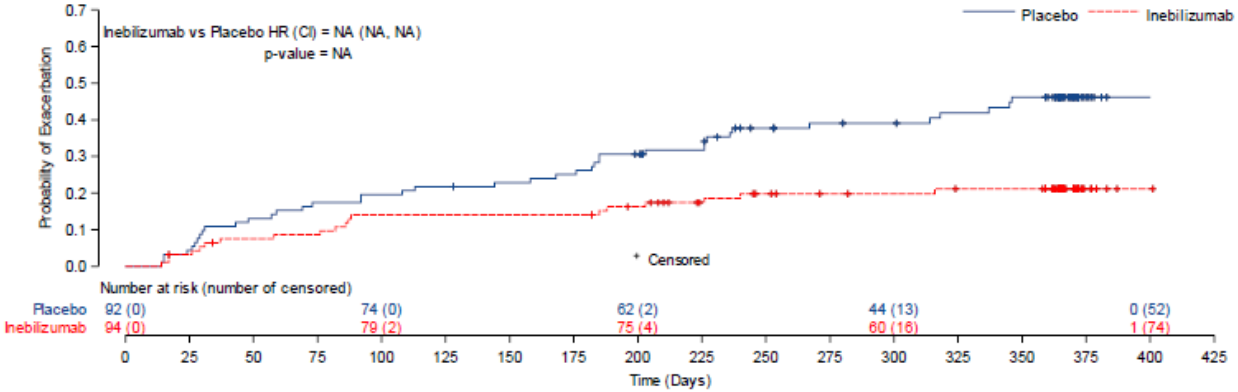
Subgroup = Region Japan



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.584. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

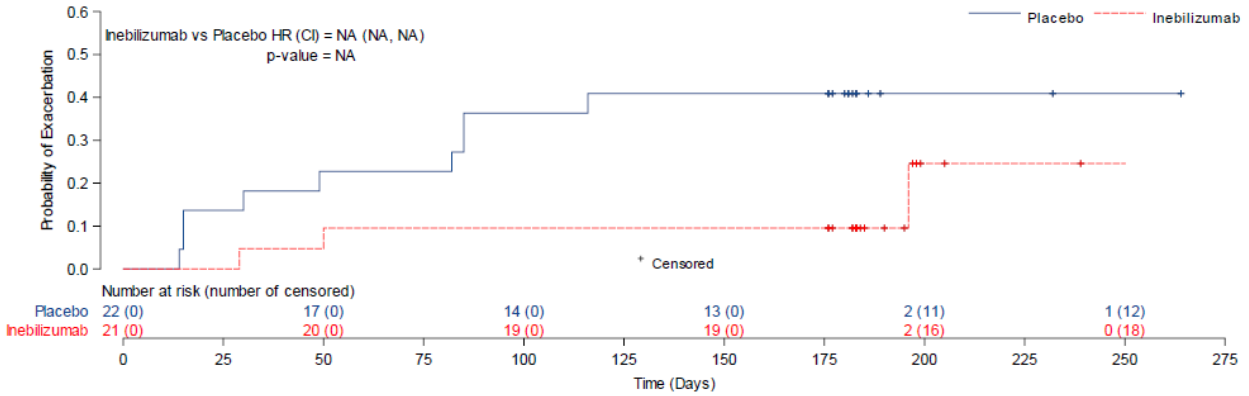
Subgroup = Region Non-Japan



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

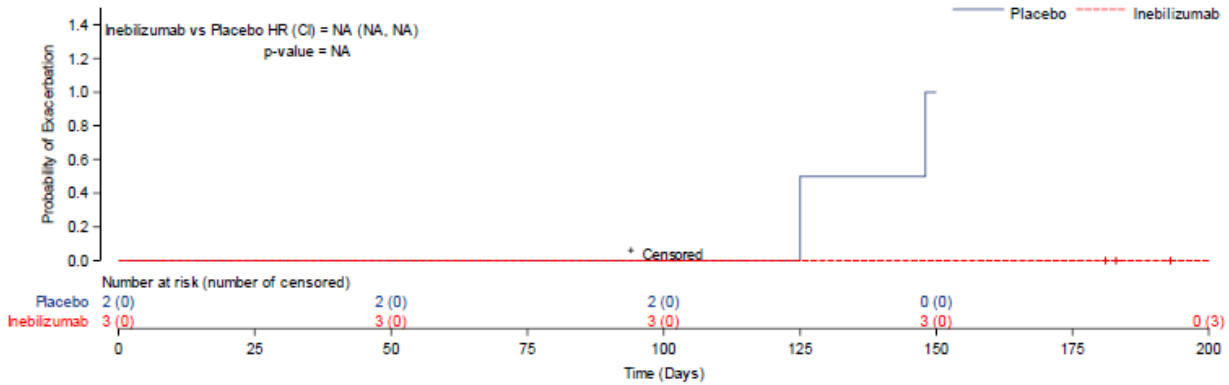
Subgroup = Age >= 18 - < 65 years



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

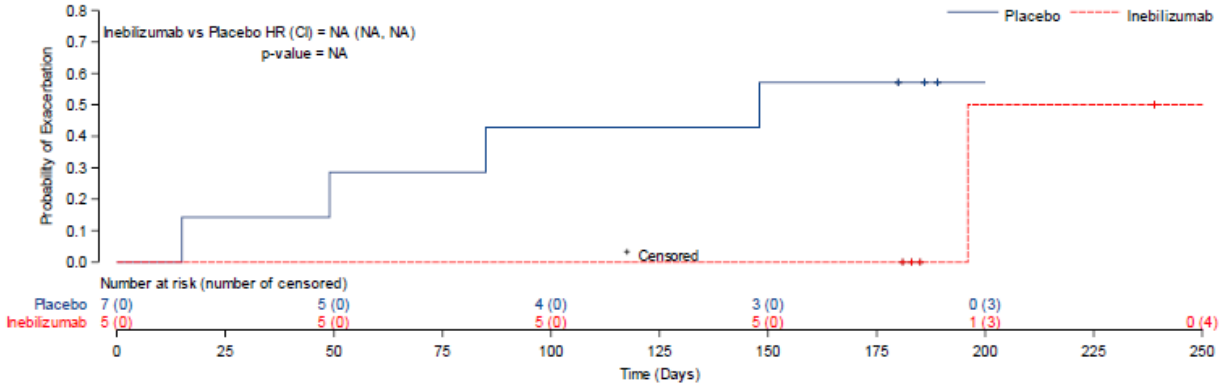
Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

Subgroup = Age >= 65 years



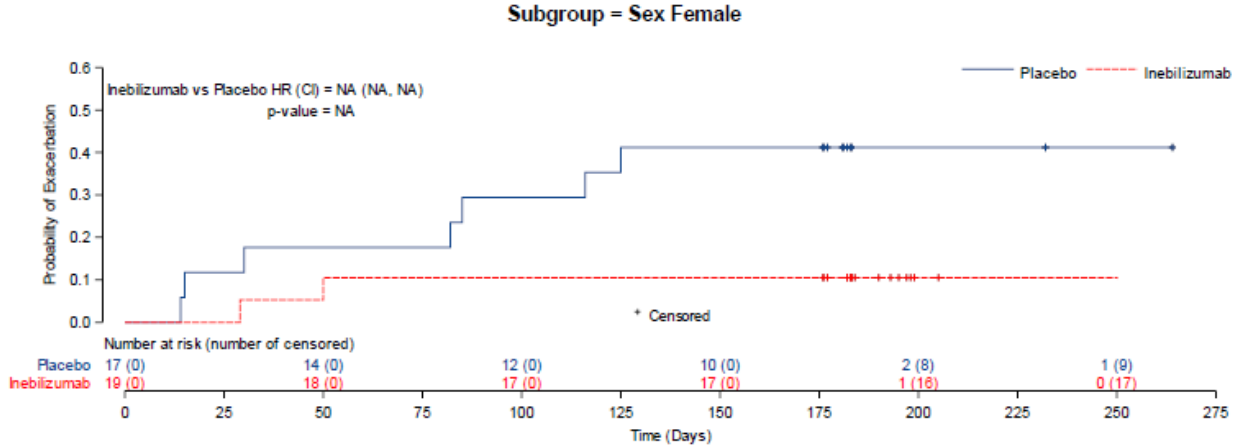
Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

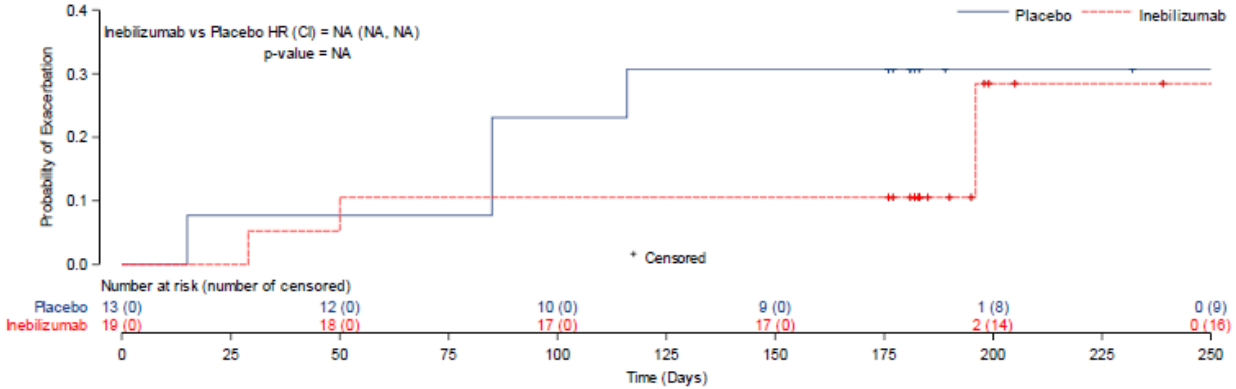
Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

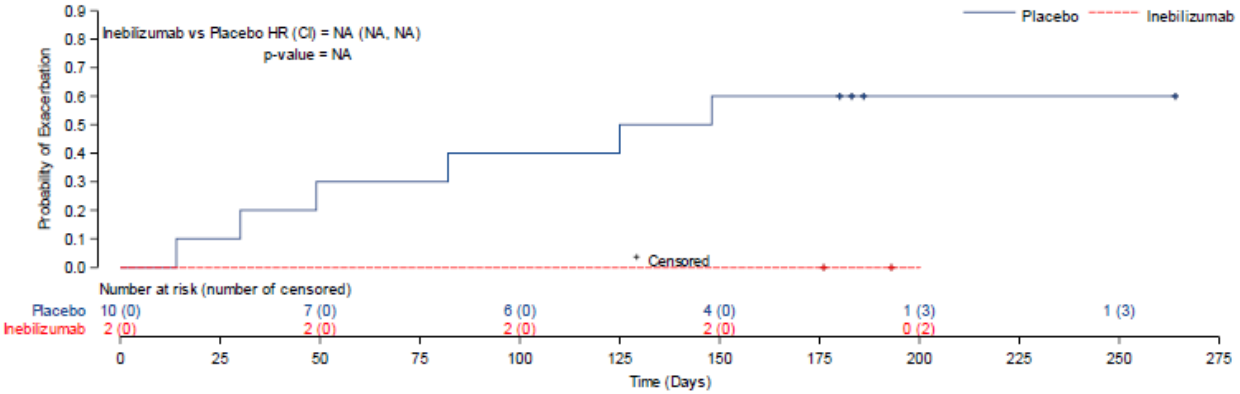
Subgroup = Baseline steroid use Prednisone <= 20 mg/day



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

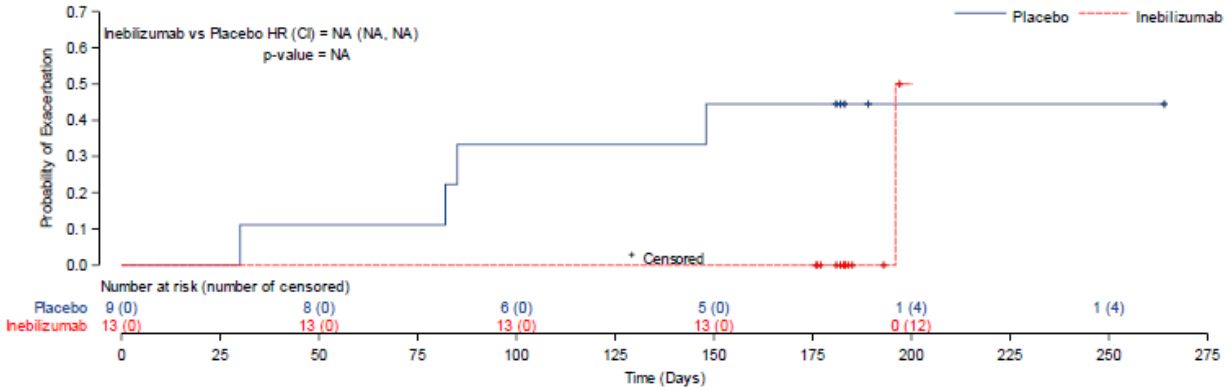
Subgroup = Baseline steroid use Prednisone > 20 mg/day



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

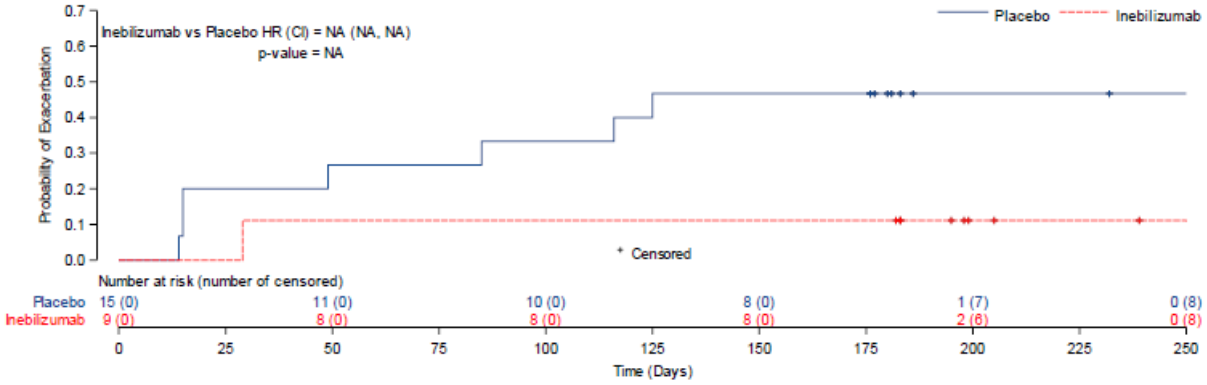
Subgroup = Baseline QMG QMG <= 15



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

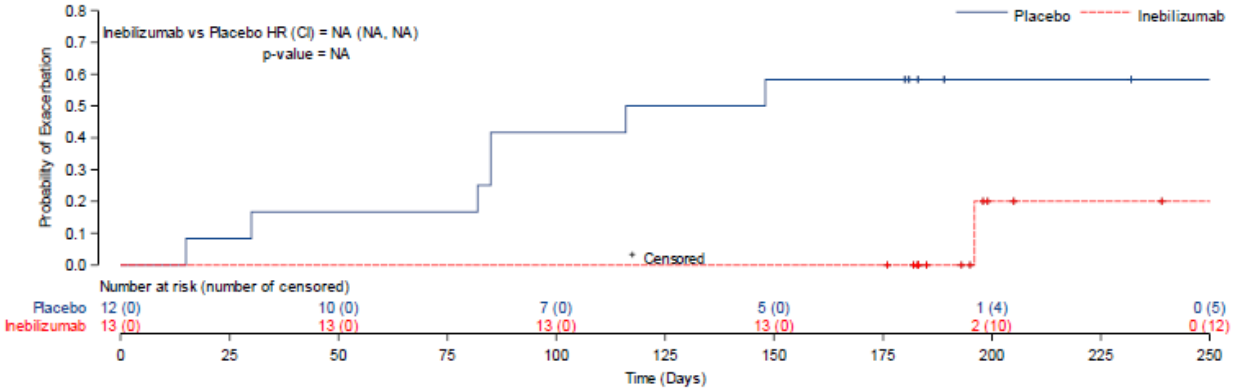
Subgroup = Baseline QMG QMG >= 16



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

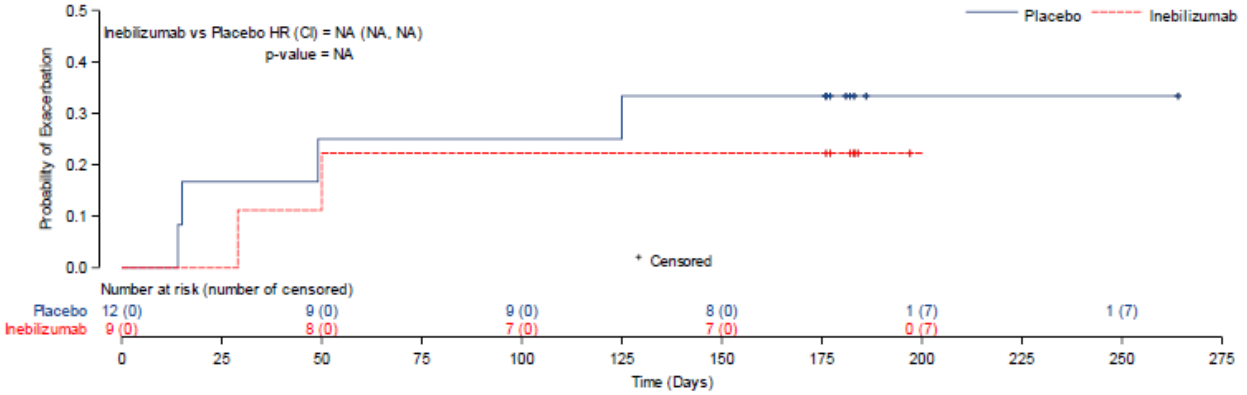
Subgroup = Baseline MGFA class II



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

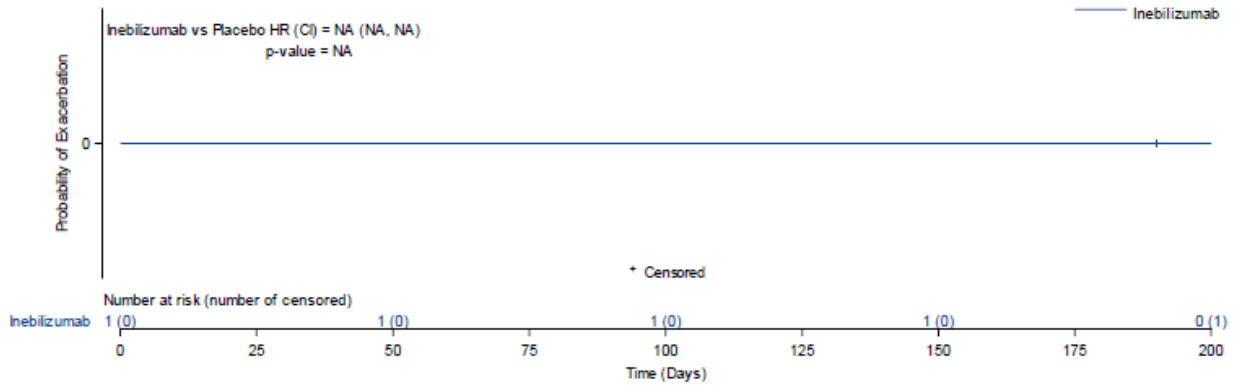
Subgroup = Baseline MGFA class III



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

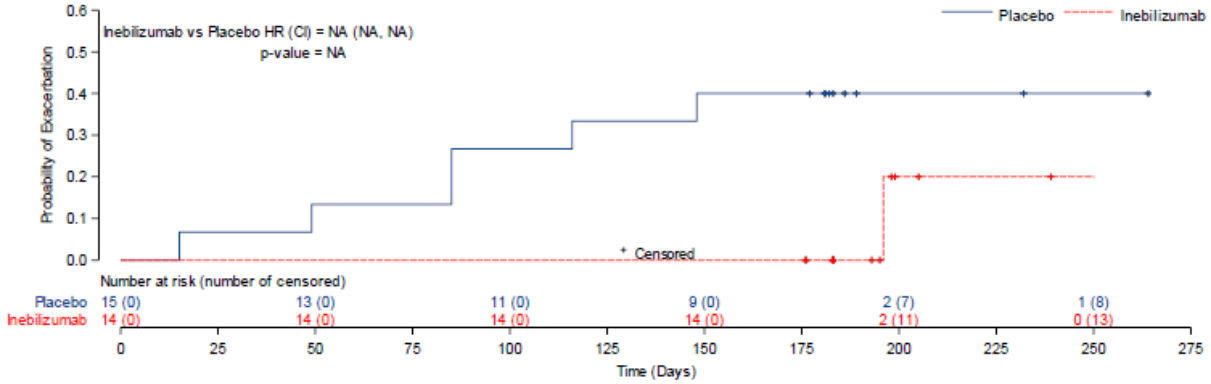
Subgroup = Baseline MGFA class IV



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

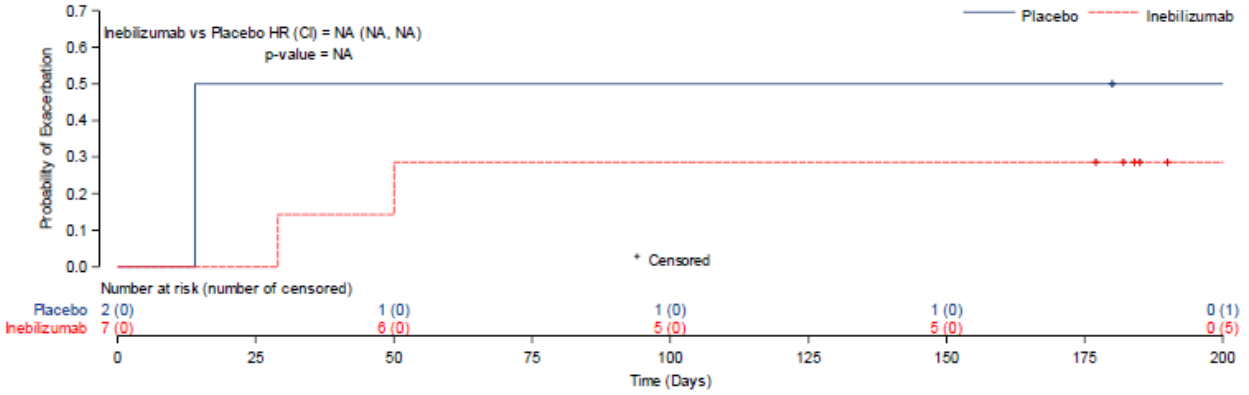
Subgroup = Region Asia



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

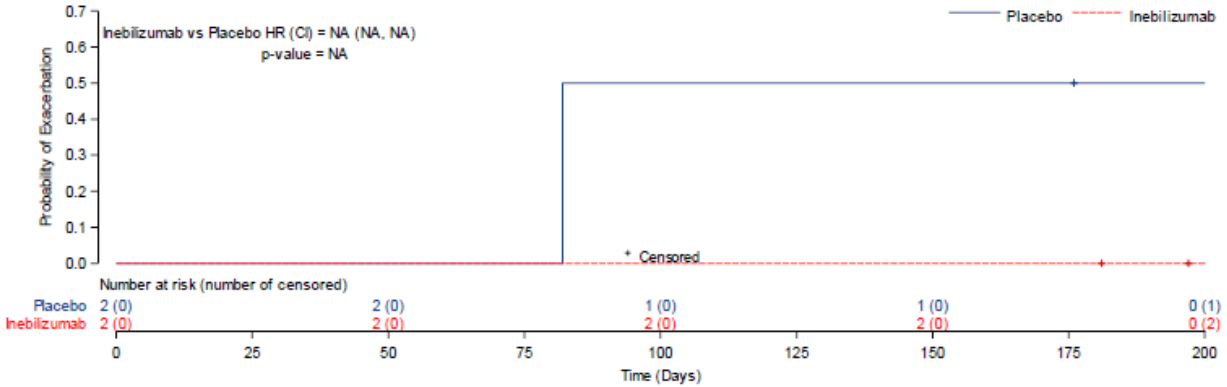
Subgroup = Region Europe



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

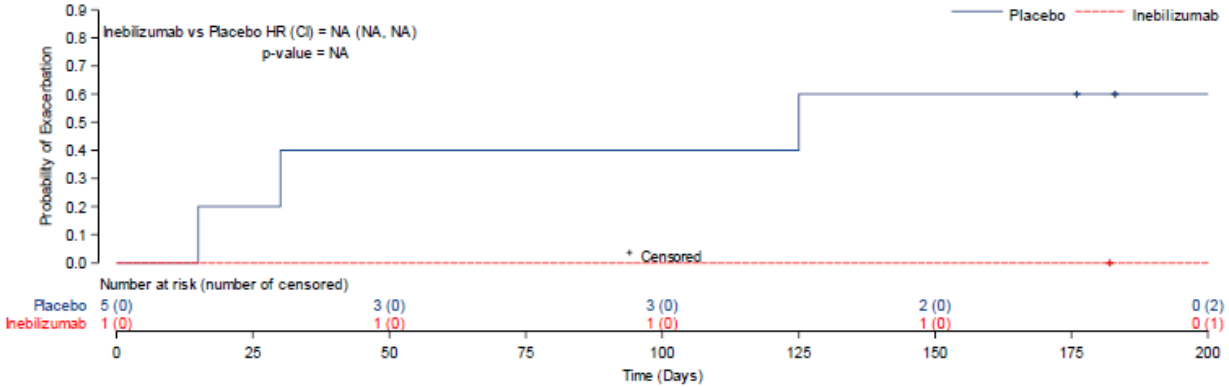
Subgroup = Region North America



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

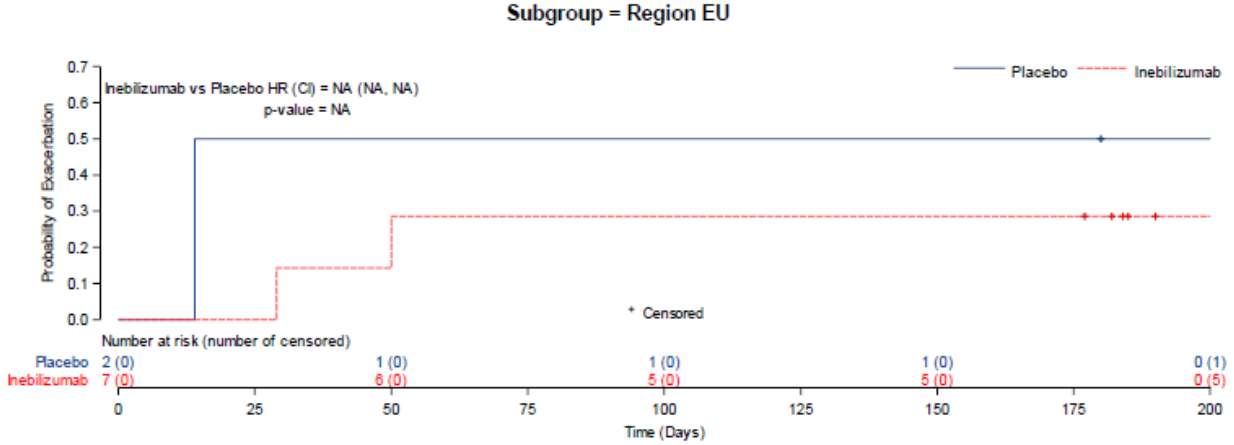
Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

Subgroup = Region Rest of the world



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

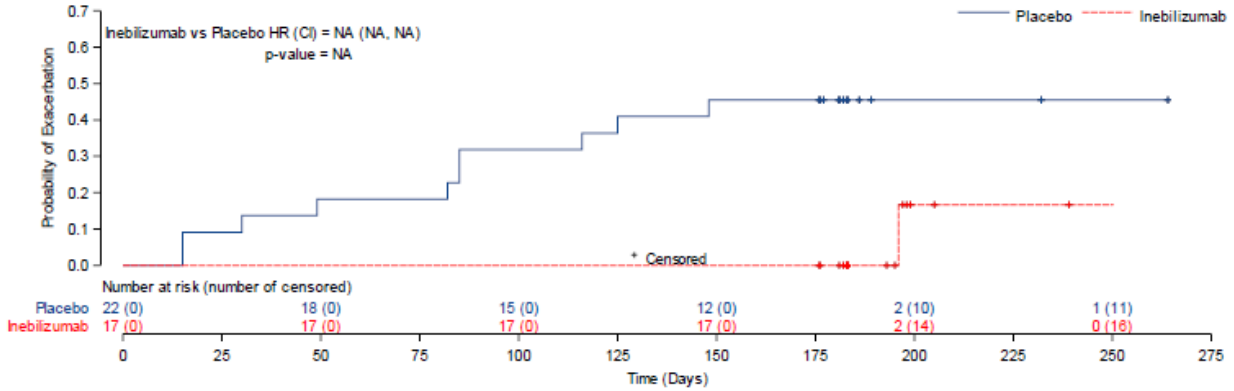
Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

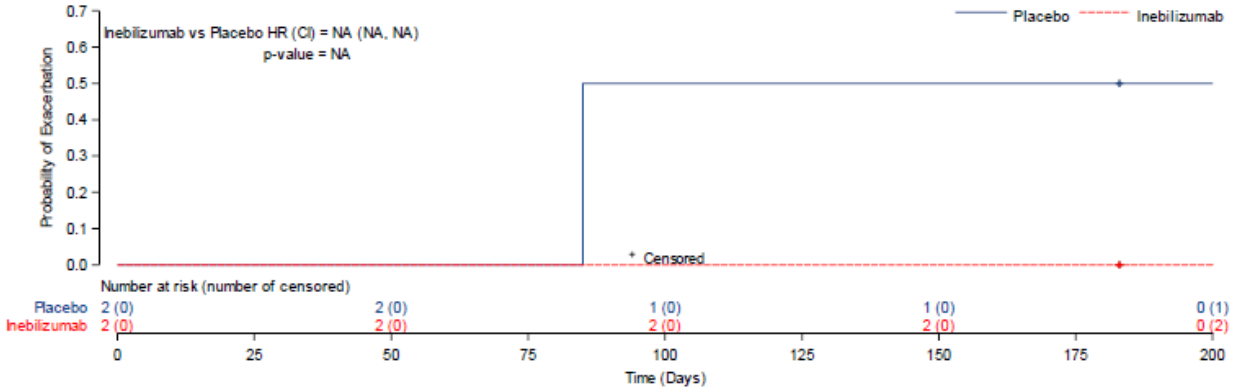
Subgroup = Region Non-EU



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

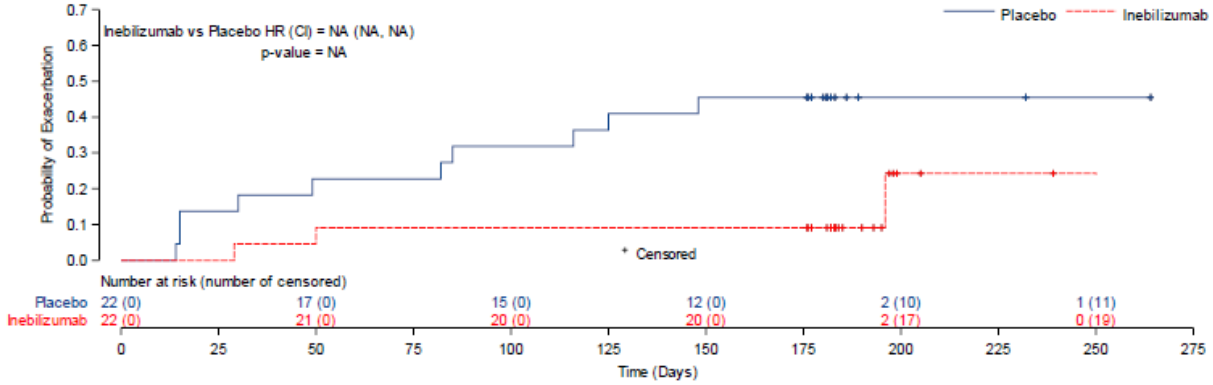
Subgroup = Region Japan



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.1.583. Subgroup Analysis: Kaplan Meier Plot for Time to First MG Exacerbation Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

Subgroup = Region Non-Japan



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

1.5.4 Jährliche Exazerbationsrate (Treatment-policy Strategie)

Subgroup	Placebo	Inebilizumab
AChR+ Population (Week 52)		
Treatment by age interaction p-value[a]		0.1970
Age		
>= 18 - < 65 years - N1	79	76
Annualized exacerbation rate[b]	1.12	0.35
Rate ratio[b]	0.31	
95% CI[b]	0.17, 0.58	
p-value[b]	0.0003	
Annualized exacerbation rate per subject		
Mean	1.28	0.39
SD	1.98	0.96
Median	0.00	0.00
Q1, Q3	0.00, 1.99	0.00, 0.00
Min, Max	0.0, 8.2	0.0, 4.9
Observed annualized exacerbation rate		
Total number of exacerbations	76	24
Total person years	71.86	70.05
Rate	1.06	0.34
Subject with exacerbation		
n	36	16
Number of exacerbations		
Mean	2.11	1.50
SD	1.28	0.89
Median	2.00	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 5.0	1.0, 4.0
>= 65 years - N1	14	19
Annualized exacerbation rate[b]	0.21	0.18
Rate ratio[b]	0.86	
95% CI[b]	0.19, 3.88	
p-value[b]	0.8391	
Annualized exacerbation rate per subject		
Mean	0.60	0.46
SD	0.99	1.38
Median	0.00	0.00
Q1, Q3	0.00, 0.98	0.00, 0.00

Subgroup	Placebo	Inebilizumab
Min, Max	0.0, 3.2	0.0, 5.8
Observed annualized exacerbation rate		
Total number of exacerbations	9	9
Total person years	11.93	17.06
Rate	0.75	0.53
Subject with exacerbation		
n	5	3
Number of exacerbations		
Mean	1.80	3.00
SD	1.30	2.65
Median	1.00	2.00
Q1, Q3	1.00, 2.00	1.00, 6.00
Min, Max	1.0, 4.0	1.0, 6.0
Treatment by sex interaction p-value[a]		0.8305
Sex		
Male - N1	45	35
Annualized exacerbation rate[b]	0.82	0.25
Rate ratio[b]	0.31	
95% CI[b]	0.11, 0.88	
p-value[b]	0.0273	
Annualized exacerbation rate per subject		
Mean	0.97	0.35
SD	1.64	1.03
Median	0.00	0.00
Q1, Q3	0.00, 1.01	0.00, 0.00
Min, Max	0.0, 7.4	0.0, 4.4
Observed annualized exacerbation rate		
Total number of exacerbations	39	9
Total person years	41.52	30.90
Rate	0.94	0.29
Subject with exacerbation		
n	18	5
Number of exacerbations		
Mean	2.17	1.80
SD	1.38	1.30

Subgroup	Placebo	Inebilizumab
Median	1.50	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 5.0	1.0, 4.0
Female - N1	48	60
Annualized exacerbation rate[b]	1.04	0.39
Rate ratio[b]	0.37	
95% CI[b]	0.18, 0.76	
p-value[b]	0.0066	
Annualized exacerbation rate per subject		
Mean	1.37	0.43
SD	2.08	1.07
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 8.2	0.0, 5.8
Observed annualized exacerbation rate		
Total number of exacerbations	46	24
Total person years	42.27	56.21
Rate	1.09	0.43
Subject with exacerbation		
n	23	14
Number of exacerbations		
Mean	2.00	1.71
SD	1.21	1.38
Median	2.00	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 5.0	1.0, 6.0
Treatment by baseline steroid use interaction p-value[a]		0.9817
Baseline steroid use		
Prednisone <= 20 mg/day - N1	54	63
Annualized exacerbation rate[b]	1.03	0.37
Rate ratio[b]	0.36	
95% CI[b]	0.15, 0.88	
p-value[b]	0.0244	
Annualized exacerbation rate per subject		
Mean	1.13	0.34

Subgroup	Placebo	Inebilizumab
SD	1.84	1.09
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 5.8
Observed annualized exacerbation rate		
Total number of exacerbations	48	20
Total person years	49.71	57.70
Rate	0.97	0.35
Subject with exacerbation		
n	20	9
Number of exacerbations		
Mean	2.40	2.22
SD	1.23	1.79
Median	2.00	1.00
Q1, Q3	1.00, 3.00	1.00, 3.00
Min, Max	1.0, 5.0	1.0, 6.0
Prednisone > 20 mg/day - N1	30	27
Annualized exacerbation rate[b]	0.00	0.00
Rate ratio[b]	0.40	
95% CI [b]	0.19, 0.85	
p-value [b]	0.0177	
Annualized exacerbation rate per subject		
Mean	1.31	0.54
SD	1.83	1.00
Median	0.98	0.00
Q1, Q3	0.00, 1.82	0.00, 1.00
Min, Max	0.0, 8.2	0.0, 4.4
Observed annualized exacerbation rate		
Total number of exacerbations	31	11
Total person years	27.08	25.21
Rate	1.14	0.44
Subject with exacerbation		
n	18	9
Number of exacerbations		
Mean	1.72	1.22
SD	1.23	0.44

Subgroup	Placebo	Inebilizumab
Median	1.00	1.00
Q1, Q3	1.00, 2.00	1.00, 1.00
Min, Max	1.0, 5.0	1.0, 2.0
Treatment by baseline QMG interaction p-value[a]		0.7909
Baseline QMG		
QMG <= 15 - N1	39	38
Annualized exacerbation rate[b]	0.77	0.27
Rate ratio[b]	0.35	
95% CI [b]	0.13, 0.92	
p-value [b]	0.0338	
Annualized exacerbation rate per subject		
Mean	0.78	0.29
SD	1.31	0.88
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	0.0, 5.5	0.0, 4.9
Observed annualized exacerbation rate		
Total number of exacerbations	24	9
Total person years	34.14	33.17
Rate	0.70	0.27
Subject with exacerbation		
n	15	6
Number of exacerbations		
Mean	1.60	1.50
SD	0.99	0.84
Median	1.00	1.00
Q1, Q3	1.00, 2.00	1.00, 2.00
Min, Max	1.0, 4.0	1.0, 3.0
QMG >= 16 - N1	52	55
Annualized exacerbation rate[b]	1.21	0.40
Rate ratio[b]	0.33	
95% CI [b]	0.16, 0.70	
p-value [b]	0.0037	
Annualized exacerbation rate per subject		
Mean	1.50	0.48

Subgroup	Placebo	Inebilizumab
SD	2.20	1.17
Median	0.00	0.00
Q1, Q3	0.00, 2.47	0.00, 0.00
Min, Max	0.0, 8.2	0.0, 5.8
Observed annualized exacerbation rate		
Total number of exacerbations	60	23
Total person years	47.64	51.93
Rate	1.26	0.44
Subject with exacerbation		
n	25	12
Number of exacerbations		
Mean	2.40	1.92
SD	1.35	1.56
Median	2.00	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 5.0	1.0, 6.0
Mean	2.40	1.92
Treatment by baseline MGFA class interaction p-value[a]		0.5369
Baseline MGFA class		
II - N1	36	43
Annualized exacerbation rate[b]	0.76	0.20
Rate ratio [b]	0.27	
95% CI [b]	0.10, 0.67	
p-value [b]	0.0051	
Annualized exacerbation rate per subject		
Mean	0.90	0.23
SD	1.31	0.79
Median	0.00	0.00
Q1, Q3	0.00, 1.15	0.00, 0.00
Min, Max	0.0, 5.0	0.0, 4.9
Observed annualized exacerbation rate		
Total number of exacerbations	32	8
Total person years	33.75	37.80
Rate	0.95	0.21
Subject with exacerbation		

Subgroup	Placebo	Inebilizumab
n	16	6
Number of exacerbations		
Mean	2.00	1.33
SD	1.37	0.82
Median	1.00	1.00
Q1, Q3	1.00, 3.00	1.00, 1.00
Min, Max	1.0, 5.0	1.0, 3.0
III - N1	49	49
Annualized exacerbation rate[b]	0.76	0.36
Rate ratio [b]	0.48	
95% CI [b]	0.20, 1.12	
p-value [b]	0.0905	
Annualized exacerbation rate per subject		
Mean	1.14	0.54
SD	1.97	1.23
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	0.0, 8.2	0.0, 5.8
Observed annualized exacerbation rate		
Total number of exacerbations	41	23
Total person years	43.34	46.22
Rate	0.95	0.50
Subject with exacerbation		
n	19	12
Number of exacerbations		
Mean	2.16	1.92
SD	1.34	1.56
Median	2.00	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 5.0	1.0, 6.0
IV - N1	7	3
Annualized exacerbation rate[b]	3.55	0.56
Rate ratio [b]	0.16	
95% CI [b]	0.01, 3.42	
p-value [b]	0.2388	
Annualized exacerbation rate per subject		

Subgroup	Placebo	Inebilizumab
Mean	3.06	0.67
SD	2.85	1.16
Median	2.95	0.00
Q1, Q3	0.98, 5.49	0.00, 2.00
Min, Max	0.0, 8.0	0.0, 2.0
Observed annualized exacerbation rate		
Total number of exacerbations	12	2
Total person years	5.66	3.09
Rate	2.12	0.65
Subject with exacerbation		
n	6	1
Number of exacerbations		
Mean	2.00	2.00
SD	0.89	NA
Median	2.00	2.00
Q1, Q3	1.00, 3.00	2.00, 2.00
Min, Max	1.0, 3.0	2.0, 2.0
Treatment by region interaction p-value[a]		0.6580
Region		
Asia - N1	39	30
Annualized exacerbation rate[b]	0.44	0.11
Rate ratio [b]	0.26	
95% CI [b]	0.08, 0.79	
p-value [b]	0.0175	
Annualized exacerbation rate per subject		
Mean	1.09	0.32
SD	2.09	0.87
Median	0.00	0.00
Q1, Q3	0.00, 1.26	0.00, 0.00
Min, Max	0.0, 8.2	0.0, 4.4
Observed annualized exacerbation rate		
Total number of exacerbations	31	6
Total person years	35.98	26.77
Rate	0.86	0.22
Subject with exacerbation		

Subgroup	Placebo	Inebilizumab
n	13	6
Number of exacerbations		
Mean	2.38	1.00
SD	1.19	0.00
Median	2.00	1.00
Q1, Q3	1.00, 3.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0
Europe - N1	39	37
Annualized exacerbation rate[b]	1.31	0.30
Rate ratio [b]	0.23	
95% CI [b]	0.09, 0.55	
p-value [b]	0.0011	
Annualized exacerbation rate per subject		
Mean	1.21	0.29
SD	1.63	0.89
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 5.5	0.0, 4.9
Observed annualized exacerbation rate		
Total number of exacerbations	42	9
Total person years	34.95	34.37
Rate	1.20	0.26
Subject with exacerbation		
n	19	6
Number of exacerbations		
Mean	2.21	1.50
SD	1.36	0.84
Median	2.00	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 5.0	1.0, 3.0
North America - N1	12	19
Annualized exacerbation rate[b]	1.09	0.34
Rate ratio [b]	0.31	
95% CI [b]	0.04, 2.27	
p-value [b]	0.2507	
Annualized exacerbation rate per subject		

Subgroup	Placebo	Inebilizumab
Mean	1.29	0.67
SD	2.26	1.58
Median	0.48	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	0.0, 7.4	0.0, 5.8
Observed annualized exacerbation rate		
Total number of exacerbations	9	13
Total person years	10.41	17.72
Rate	0.86	0.73
Subject with exacerbation		
n	6	4
Number of exacerbations		
Mean	1.50	3.25
SD	1.22	2.22
Median	1.00	3.00
Q1, Q3	1.00, 1.00	1.50, 5.00
Min, Max	1.0, 4.0	1.0, 6.0
Rest of the world - N1	3	9
Annualized exacerbation rate[b]	0.80	0.66
Rate ratio [b]	0.82	
95% CI [b]	0.16, 4.21	
p-value [b]	0.8139	
Annualized exacerbation rate per subject		
Mean	1.39	0.55
SD	0.66	0.88
Median	1.03	0.00
Q1, Q3	0.99, 2.15	0.00, 0.98
Min, Max	1.0, 2.1	0.0, 2.0
Observed annualized exacerbation rate		
Total number of exacerbations	3	5
Total person years	2.44	8.25
Rate	1.23	0.61
Subject with exacerbation		
n	3	3
Number of exacerbations		
Mean	1.00	1.67

Subgroup	Placebo	Inebilizumab
SD	0.00	0.58
Median	1.00	2.00
Q1, Q3	1.00, 1.00	1.00, 2.00
Min, Max	1.0, 1.0	1.0, 2.0
Treatment by region interaction p-value[a]		0.2096
Region		
EU - N1	39	37
Annualized exacerbation rate[b]	1.31	0.30
Rate ratio [b]	0.23	
95% CI [b]	0.09, 0.55	
p-value [b]	0.0011	
Annualized exacerbation rate per subject		
Mean	1.21	0.29
SD	1.63	0.89
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 5.5	0.0, 4.9
Observed annualized exacerbation rate		
Total number of exacerbations	42	9
Total person years	34.95	34.37
Rate	1.20	0.26
Subject with exacerbation		
n	19	6
Number of exacerbations		
Mean	2.21	1.50
SD	1.36	0.84
Median	2.00	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 5.0	1.0, 3.0
Non-EU - N1	54	58
Annualized exacerbation rate[b]	0.65	0.32
Rate ratio [b]	0.49	
95% CI [b]	0.23, 1.05	
p-value [b]	0.0653	
Annualized exacerbation rate per subject		

Subgroup	Placebo	Inebilizumab
Mean	1.15	0.47
SD	2.05	1.14
Median	0.00	0.00
Q1, Q3	0.00, 1.03	0.00, 0.00
Min, Max	0.0, 8.2	0.0, 5.8
Observed annualized exacerbation rate		
Total number of exacerbations	43	24
Total person years	48.84	52.75
Rate	0.88	0.45
Subject with exacerbation		
n	22	13
Number of exacerbations		
Mean	1.95	1.85
SD	1.21	1.52
Median	1.00	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 4.0	1.0, 6.0
Treatment by region interaction p-value[a]		NA
Region		
Japan - N1	1	1
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	8.03	0.00
SD	NA	NA
Median	8.03	0.00
Q1, Q3	8.03, 8.03	0.00, 0.00
Min, Max	8.0, 8.0	0.0, 0.0
Observed annualized exacerbation rate		
Total number of exacerbations	2	0
Total person years	0.25	1.00
Rate	8.03	0.00
Subject with exacerbation		

Subgroup	Placebo	Inebilizumab
n	1	0
Number of exacerbations		
Mean	2.00	NA
SD	NA	NA
Median	2.00	NA
Q1, Q3	2.00, 2.00	NA, NA
Min, Max	2.0, 2.0	NA, NA
Non-Japan - N1	92	94
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	1.10	0.41
SD	1.75	1.06
Median	0.00	0.00
Q1, Q3	0.00, 1.54	0.00, 0.00
Min, Max	0.0, 8.2	0.0, 5.8
Observed annualized exacerbation rate		
Total number of exacerbations	83	33
Total person years	83.54	86.12
Rate	0.99	0.38
Subject with exacerbation		
n	40	19
Number of exacerbations		
Mean	2.08	1.74
SD	1.29	1.33
Median	1.50	1.00
Q1, Q3	1.00, 3.00	1.00, 2.00
Min, Max	1.0, 5.0	1.0, 6.0
MuSK+ Population (Week 26)		
Treatment by age interaction p-value[a]		NA
Age		
>= 18 - < 65 years - N1	22	21
Annualized exacerbation rate[b]	NA	NA

Subgroup	Placebo	Inebilizumab
Rate ratio[b]	NA	
95% CI[b]	NA, NA	
p-value[b]	NA	
Annualized exacerbation rate per subject		
Mean	1.79	0.27
SD	2.76	0.67
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 1.9
Observed annualized exacerbation rate		
Total number of exacerbations	20	3
Total person years	11.38	10.96
Rate	1.76	0.27
Subject with exacerbation		
n	9	3
Number of exacerbations		
Mean	2.22	1.00
SD	1.39	0.00
Median	2.00	1.00
Q1, Q3	1.00, 4.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0
>= 65 years - N1	2	3
Annualized exacerbation rate[b]	NA	NA
Rate ratio[b]	NA	
95% CI[b]	NA, NA	
p-value[b]	NA	
Annualized exacerbation rate per subject		
Mean	2.00	0.00
SD	0.09	0.00
Median	2.00	0.00
Q1, Q3	1.94, 2.06	0.00, 0.00
Min, Max	1.9, 2.1	0.0, 0.0
Observed annualized exacerbation rate		
Total number of exacerbations	2	0
Total person years	1.00	1.52
Rate	2.00	0.00

Subgroup	Placebo	Inebilizumab
Subject with exacerbation		
n	2	0
Number of exacerbations		
Mean	1.00	NA
SD	0.00	NA
Median	1.00	NA
Q1, Q3	1.00, 1.00	NA, NA
Min, Max	1.0, 1.0	NA, NA
Treatment by sex interaction p-value[a]		NA
Sex		
Male - N1	7	5
Annualized exacerbation rate[b]	NA	NA
Rate ratio[b]	NA	
95% CI[b]	NA, NA	
p-value[b]	NA	
Annualized exacerbation rate per subject		
Mean	2.30	0.35
SD	2.93	0.79
Median	1.92	0.00
Q1, Q3	0.00, 4.10	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 1.8
Observed annualized exacerbation rate		
Total number of exacerbations	8	1
Total person years	3.51	2.73
Rate	2.28	0.37
Subject with exacerbation		
n	4	1
Number of exacerbations		
Mean	2.00	1.00
SD	1.41	NA
Median	1.50	1.00
Q1, Q3	1.00, 3.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0
Female - N1	17	19
Annualized exacerbation rate[b]	NA	NA

Subgroup	Placebo	Inebilizumab
Rate ratio[b]	NA	
95% CI[b]	NA, NA	
p-value[b]	NA	
Annualized exacerbation rate per subject		
Mean	1.60	0.20
SD	2.57	0.61
Median	0.00	0.00
Q1, Q3	0.00, 1.99	0.00, 0.00
Min, Max	0.0, 7.7	0.0, 1.9
Observed annualized exacerbation rate		
Total number of exacerbations	14	2
Total person years	8.87	9.76
Rate	1.58	0.20
Subject with exacerbation		
n	7	2
Number of exacerbations		
Mean	2.00	1.00
SD	1.41	0.00
Median	1.00	1.00
Q1, Q3	1.00, 4.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0
Treatment by baseline steroid use interaction p-value[a]		NA
Baseline steroid use		
Prednisone <= 20 mg/day - N1	13	19
Annualized exacerbation rate[b]	NA	NA
Rate ratio[b]	NA	
95% CI[b]	NA, NA	
p-value[b]	NA	
Annualized exacerbation rate per subject		
Mean	0.77	0.30
SD	1.32	0.70
Median	0.00	0.00
Q1, Q3	0.00, 1.93	0.00, 0.00
Min, Max	0.0, 4.1	0.0, 1.9
Observed annualized exacerbation rate		

Subgroup	Placebo	Inebilizumab
Total number of exacerbations	5	3
Total person years	6.60	9.93
Rate	0.76	0.30
Subject with exacerbation		
n	4	3
Number of exacerbations		
Mean	1.25	1.00
SD	0.50	0.00
Median	1.00	1.00
Q1, Q3	1.00, 1.50	1.00, 1.00
Min, Max	1.0, 2.0	1.0, 1.0
Prednisone > 20 mg/day - N1	10	2
Annualized exacerbation rate[b]	NA	NA
Rate ratio[b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	3.14	0.00
SD	3.45	0.00
Median	2.00	0.00
Q1, Q3	0.00, 7.61	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 0.0
Observed annualized exacerbation rate		
Total number of exacerbations	16	0
Total person years	5.26	1.01
Rate	3.04	0.00
Subject with exacerbation		
n	6	0
Number of exacerbations		
Mean	2.67	NA
SD	1.51	NA
Median	3.00	NA
Q1, Q3	1.00, 4.00	NA, NA
Min, Max	1.0, 4.0	NA, NA
Treatment by baseline QMG interaction p-value[a]		NA

Subgroup	Placebo	Inebilizumab
Baseline QMG		
QMG <= 15 - N1	9	13
Annualized exacerbation rate[b]	NA	NA
Rate ratio[b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	1.75	0.14
SD	2.63	0.49
Median	0.00	0.00
Q1, Q3	0.00, 2.06	0.00, 0.00
Min, Max	0.0, 7.6	0.0, 1.8
Observed annualized exacerbation rate		
Total number of exacerbations	8	1
Total person years	4.74	6.59
Rate	1.69	0.15
Subject with exacerbation		
n	4	1
Number of exacerbations		
Mean	2.00	1.00
SD	1.41	NA
Median	1.50	1.00
Q1, Q3	1.00, 3.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0
QMG >= 16 - N1	15	9
Annualized exacerbation rate[b]	NA	NA
Rate ratio[b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	1.84	0.21
SD	2.73	0.64
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 1.9
Observed annualized exacerbation rate		

Subgroup	Placebo	Inebilizumab
Total number of exacerbations	14	1
Total person years	7.64	4.86
Rate	1.83	0.21
Subject with exacerbation		
n	7	1
Number of exacerbations		
Mean	2.00	1.00
SD	1.41	NA
Median	1.00	1.00
Q1, Q3	1.00, 4.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0
Treatment by baseline MGFA class interaction p-value[a]		NA
Baseline MGFA class		
II - N1	12	13
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	1.98	0.14
SD	2.34	0.49
Median	1.96	0.00
Q1, Q3	0.00, 3.06	0.00, 0.00
Min, Max	0.0, 7.6	0.0, 1.8
Observed annualized exacerbation rate		
Total number of exacerbations	12	1
Total person years	6.15	6.92
Rate	1.95	0.14
Subject with exacerbation		
n	7	1
Number of exacerbations		
Mean	1.71	1.00
SD	1.11	NA
Median	1.00	1.00
Q1, Q3	1.00, 2.00	1.00, 1.00

Subgroup	Placebo	Inebilizumab
Min, Max	1.0, 4.0	1.0, 1.0
III - N1	12	9
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	1.63	0.43
SD	3.00	0.85
Median	0.00	0.00
Q1, Q3	0.00, 1.93	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 1.9
Observed annualized exacerbation rate		
Total number of exacerbations	10	2
Total person years	6.23	4.54
Rate	1.61	0.44
Subject with exacerbation		
n	4	2
Number of exacerbations		
Mean	2.50	1.00
SD	1.73	0.00
Median	2.50	1.00
Q1, Q3	1.00, 4.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0
IV - N1	0	1
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	NA	0.00
SD	NA	NA
Median	NA	0.00
Q1, Q3	NA, NA	0.00, 0.00
Min, Max	NA, NA	0.0, 0.0
Observed annualized exacerbation rate		

Subgroup	Placebo	Inebilizumab
Total number of exacerbations	0	0
Total person years	0	0.52
Rate	NA	0.00
Subject with exacerbation		
n	0	0
Number of exacerbations		
Mean	NA	NA
SD	NA	NA
Median	NA	NA
Q1, Q3	NA, NA	NA, NA
Min, Max	NA, NA	NA, NA
Treatment by region interaction p-value[a]		NA
Region		
Asia - N1	15	14
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	1.34	0.13
SD	2.23	0.47
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 1.8
Observed annualized exacerbation rate		
Total number of exacerbations	10	1
Total person years	7.85	7.40
Rate	1.27	0.14
Subject with exacerbation		
n	6	1
Number of exacerbations		
Mean	1.67	1.00
SD	1.21	NA
Median	1.00	1.00
Q1, Q3	1.00, 2.00	1.00, 1.00

Subgroup	Placebo	Inebilizumab
Min, Max	1.0, 4.0	1.0, 1.0
Europe - N1	2	7
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	3.87	0.55
SD	5.47	0.94
Median	3.87	0.00
Q1, Q3	0.00, 7.73	0.00, 1.92
Min, Max	0.0, 7.7	0.0, 1.9
Observed annualized exacerbation rate		
Total number of exacerbations	4	2
Total person years	1.01	3.55
Rate	3.96	0.56
Subject with exacerbation		
n	1	2
Number of exacerbations		
Mean	4.00	1.00
SD	NA	0.00
Median	4.00	1.00
Q1, Q3	4.00, 4.00	1.00, 1.00
Min, Max	4.0, 4.0	1.0, 1.0
North America - N1	2	2
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	2.03	0.00
SD	2.87	0.00
Median	2.03	0.00
Q1, Q3	0.00, 4.06	0.00, 0.00
Min, Max	0.0, 4.1	0.0, 0.0
Observed annualized exacerbation rate		

Subgroup	Placebo	Inebilizumab
Total number of exacerbations	2	0
Total person years	0.97	1.03
Rate	2.05	0.00
Subject with exacerbation		
n	1	0
Number of exacerbations		
Mean	2.00	NA
SD	NA	NA
Median	2.00	NA
Q1, Q3	2.00, 2.00	NA, NA
Min, Max	2.0, 2.0	NA, NA
Rest of the world - N1	5	1
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	2.29	0.00
SD	3.12	NA
Median	1.92	0.00
Q1, Q3	0.00, 1.94	0.00, 0.00
Min, Max	0.0, 7.6	0.0, 0.0
Observed annualized exacerbation rate		
Total number of exacerbations	6	0
Total person years	2.54	0.50
Rate	2.36	0.00
Subject with exacerbation		
n	3	0
Number of exacerbations		
Mean	2.00	NA
SD	1.73	NA
Median	1.00	NA
Q1, Q3	1.00, 4.00	NA, NA
Min, Max	1.0, 4.0	NA, NA
Treatment by region interaction p-value[a]		NA

Subgroup	Placebo	Inebilizumab
Region		
EU - N1	2	7
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	3.87	0.55
SD	5.47	0.94
Median	3.87	0.00
Q1, Q3	0.00, 7.73	0.00, 1.92
Min, Max	0.0, 7.7	0.0, 1.9
Observed annualized exacerbation rate		
Total number of exacerbations	4	2
Total person years	1.01	3.55
Rate	3.96	0.56
Subject with exacerbation		
n	1	2
Number of exacerbations		
Mean	4.00	1.00
SD	NA	0.00
Median	4.00	1.00
Q1, Q3	4.00, 4.00	1.00, 1.00
Min, Max	4.0, 4.0	1.0, 1.0
Non-EU - N1	22	17
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	1.62	0.10
SD	2.40	0.43
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 1.8
Observed annualized exacerbation rate		

Subgroup	Placebo	Inebilizumab
Total number of exacerbations	18	1
Total person years	11.37	8.94
Rate	1.58	0.11
Subject with exacerbation		
n	10	1
Number of exacerbations		
Mean	1.80	1.00
SD	1.23	NA
Median	1.00	1.00
Q1, Q3	1.00, 2.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0
Treatment by region interaction p-value[a]		NA
Region		
Japan - N1	2	2
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	2.05	0.00
SD	2.90	0.00
Median	2.05	0.00
Q1, Q3	0.00, 4.10	0.00, 0.00
Min, Max	0.0, 4.1	0.0, 0.0
Observed annualized exacerbation rate		
Total number of exacerbations	2	0
Total person years	0.99	1.00
Rate	2.02	0.00
Subject with exacerbation		
n	1	0
Number of exacerbations		
Mean	2.00	NA
SD	NA	NA
Median	2.00	NA
Q1, Q3	2.00, 2.00	NA, NA

Subgroup	Placebo	Inebilizumab
Min, Max	2.0, 2.0	NA, NA
Non-Japan - N1	22	22
Annualized exacerbation rate[b]	NA	NA
Rate ratio [b]	NA	
95% CI [b]	NA, NA	
p-value [b]	NA	
Annualized exacerbation rate per subject		
Mean	1.78	0.26
SD	2.68	0.66
Median	0.00	0.00
Q1, Q3	0.00, 2.00	0.00, 0.00
Min, Max	0.0, 8.0	0.0, 1.9
Observed annualized exacerbation rate		
Total number of exacerbations	20	3
Total person years	11.39	11.48
Rate	1.76	0.26
Subject with exacerbation		
n	10	3
Number of exacerbations		
Mean	2.00	1.00
SD	1.41	0.00
Median	1.00	1.00
Q1, Q3	1.00, 4.00	1.00, 1.00
Min, Max	1.0, 4.0	1.0, 1.0

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. N1 = Number of subjects in each subgroup level. The denominator of the percentage is the N1 under each subgroup.
An exacerbation is defined as Use of protocol defined rescue therapy, or Myasthenic crisis or Significant symptomatic worsening. Annual exacerbation rate per subject = 365.25*total number of exacerbations for a subject/total duration of follow-up for this subject (days).
[a] Estimated from the negative binomial regression with common covariate of treatment group, baseline steroid use (daily prednisone dose <= 5 mg vs daily prednisone dose > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), baseline MG-ADL score, treatment × subgroup variable. The logarithm of the subject's corresponding follow-up time is used as an offset variable.
[b] Estimated from the negative binomial regression with common covariate of treatment group, baseline steroid use (daily prednisone dose <= 5 mg vs daily prednisone dose > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score. The logarithm of the subject's corresponding follow-up time is used as an offset variable.

1.6 Rescue-Therapien

1.6.1 Anteil an Patientinnen und Patienten mit Rescue-Therapie

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	28 / 79 (35.4)	9 / 76 (11.8)	0.25 (0.11, 0.58)	0.0011	0.33 (0.17, 0.64)	0.0006	-20.70 (-33.10, -8.30)	0.0011	
>= 65 years	4 / 14 (28.6)	2 / 19 (10.5)	0.47 (0.08, 2.95)	0.4223	0.37 (0.09, 1.51)	0.3631	-10.62 (-38.08, 16.85)	0.4488	
Sex									1.0000
Male	14 / 45 (31.1)	3 / 35 (8.6)	0.26 (0.07, 0.95)	0.0423	0.28 (0.09, 0.80)	0.0256	-18.72 (-35.92, -1.53)	0.0328	
Female	18 / 48 (37.5)	8 / 60 (13.3)	0.27 (0.10, 0.69)	0.0062	0.36 (0.17, 0.73)	0.0059	-21.95 (-38.36, -5.54)	0.0088	
Baseline steroid use									1.0000
Prednisone <= 20 mg/day	13 / 54 (24.1)	5 / 63 (7.9)	0.31 (0.11, 0.92)	0.0356	0.33 (0.13, 0.83)	0.0207	-14.33 (-28.29, -0.37)	0.0442	
Prednisone > 20 mg/day	16 / 30 (53.3)	5 / 27 (18.5)	0.22 (0.06, 0.76)	0.0166	0.35 (0.15, 0.76)	0.0124	-29.49 (-63.23, 4.24)	0.0866	
Baseline QMG									0.6732
QMG <= 15	11 / 39 (28.2)	2 / 38 (5.3)	0.16 (0.04, 0.70)	0.0148	0.19 (0.05, 0.68)	0.0127	-22.03 (-39.10, -4.97)	0.0114	
QMG >= 16	20 / 52 (38.5)	8 / 55 (14.5)	0.29 (0.11, 0.73)	0.0085	0.38 (0.18, 0.76)	0.0077	-22.16 (-38.50, -5.83)	0.0078	
Baseline MGFA class									0.3995
II	12 / 36 (33.3)	3 / 43 (7.0)	0.20 (0.05, 0.75)	0.0172	0.21 (0.07, 0.63)	0.0038	-13.74 (-31.77, 4.30)	0.1355	
III	14 / 49 (28.6)	7 / 49 (14.3)	0.44 (0.16, 1.18)	0.1023	0.50 (0.22, 1.09)	0.1385	-13.62 (-29.70, 2.46)	0.0968	
IV	6 / 7 (85.7)	1 / 3 (33.3)	ND	ND	0.39 (0.07, 1.15)	0.1833	ND	ND	
Region									0.2154
Asia	9 / 39 (23.1)	4 / 30 (13.3)	0.52 (0.15, 1.81)	0.3031	0.58 (0.20, 1.58)	0.3650	-9.39 (-27.22, 8.43)	0.3018	
Europe	16 / 39 (41.0)	3 / 37 (8.1)	0.12 (0.03, 0.47)	0.0023	0.20 (0.06, 0.56)	0.0012	-26.83 (-44.43, -9.23)	0.0028	

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
North America	4 / 12 (33.3)	3 / 19 (15.8)	0.43 (0.08, 2.31)	0.3237	0.47 (0.14, 1.65)	0.3839	-16.24 (-48.73, 16.26)	0.3274	
Rest of the world	3 / 3 (100.0)	1 / 9 (11.1)	0.03 (0.00, 2.87)	0.1305	0.17 (0.04, 0.68)	0.0182	70.37 (-123.35, -17.40)	0.0092	
Region									0.2524
EU	16 / 39 (41.0)	3 / 37 (8.1)	0.12 (0.03, 0.47)	0.0023	0.20 (0.06, 0.56)	0.0012	-26.83 (-44.43, -9.23)	0.0028	
Non-EU	16 / 54 (29.6)	8 / 58 (13.8)	0.40 (0.16, 1.03)	0.0565	0.47 (0.22, 0.97)	0.0640	-14.64 (-29.87, 0.60)	0.0597	
Region									NA
Japan	1 / 1 (100.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	31 / 92 (33.7)	11 / 94 (11.7)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	4 / 22 (18.2)	1 / 21 (4.8)	NA	NA	NA	NA	NA	NA	
>= 65 years	2 / 2 (100.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	
Sex									NA
Male	3 / 7 (42.9)	0 / 5 (0.0)	NA	NA	NA	NA	NA	NA	
Female	3 / 17 (17.6)	1 / 19 (5.3)	NA	NA	NA	NA	NA	NA	
Baseline steroid use									NA
Prednisone <= 20 mg/day	2 / 13 (15.4)	1 / 19 (5.3)	NA	NA	NA	NA	NA	NA	
Prednisone > 20 mg/day	4 / 10 (40.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	
Baseline QMG									NA
QMG <= 15	2 / 9 (22.2)	0 / 13 (0.0)	NA	NA	NA	NA	NA	NA	
QMG >= 16	4 / 15 (26.7)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	
Baseline MGFA class									NA
II	4 / 12 (33.3)	0 / 13 (0.0)	NA	NA	NA	NA	NA	NA	
III	2 / 12 (16.7)	1 / 9 (11.1)	NA	NA	NA	NA	NA	NA	

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
IV	0 / 0 (-)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	4 / 15 (26.7)	0 / 14 (0.0)	NA	NA	NA	NA	NA	NA	
Europe	0 / 2 (0.0)	1 / 7 (14.3)	NA	NA	NA	NA	NA	NA	
North America	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	2 / 5 (40.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	0 / 2 (0.0)	1 / 7 (14.3)	NA	NA	NA	NA	NA	NA	
Non-EU	6 / 22 (27.3)	0 / 17 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	1 / 2 (50.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	5 / 22 (22.7)	1 / 22 (4.5	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
IVIg = Intravenous immunoglobulin; PLEX = Plasma exchange. MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects in each subgroup level. CI = Confidence interval.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.6.2 Zeit bis zur ersten Rescue-Therapie (Treatment-policy Strategie)

Subgroup	Placebo	Inebilizumab
AChR+ Population (Week 52)		
Treatment by age interaction p-value[a]		0.9472
Age		
>= 18 - < 65 years		
Subjects with rescue therapy - n / N1 (%)	28 / 79 (35.4)	9 / 76 (11.8)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	0.31	
95% CI[c]	0.15, 0.66	
p-value[c]	0.0022	
>= 65 years		
Subjects with rescue therapy - n / N1 (%)	4 / 14 (28.6)	2 / 19 (10.5)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	7.43, NA	NA, NA
Hazard ratio[c]	0.29	
95% CI[c]	0.04, 1.93	
p-value[c]	0.1985	
Treatment by sex interaction p-value[a]		0.9852
Sex		
Male		
Subjects with rescue therapy - n / N1 (%)	14 / 45 (31.1)	3 / 35 (8.6)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	11.96, NA	NA, NA
Hazard ratio[c]	0.29	
95% CI[c]	0.08, 1.03	
p-value[c]	0.0555	
Female		
Subjects with rescue therapy - n / N1 (%)	18 / 48 (37.5)	8 / 60 (13.3)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	11.17, NA	NA, NA
Hazard ratio[c]	0.30	
95% CI[c]	0.13, 0.70	
p-value[c]	0.0056	
Treatment by baseline steroid use interaction p-value[a]		0.8012

Subgroup	Placebo	Inebilizumab
Baseline steroid use		
Prednisone <= 20 mg/day		
Subjects with rescue therapy - n / N1 (%)	13 / 54 (24.1)	5 / 63 (7.9)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	0.35	
95% CI[c]	0.13, 1.00	
p-value[c]	0.0503	
Prednisone > 20 mg/day		
Subjects with rescue therapy - n / N1 (%)	16 / 30 (53.3)	5 / 27 (18.5)
Median time to first rescue therapy (months)[b]	11.37	NA
95% CI[b]	6.67, NA	NA, NA
Hazard ratio[c]	0.30	
95% CI[c]	0.11, 0.81	
p-value[c]	0.0184	
Treatment by baseline QMG interaction p-value[a]		0.5255
Baseline QMG		
QMG <= 15		
Subjects with rescue therapy - n / N1 (%)	11 / 39 (28.2)	2 / 38 (5.3)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	0.17	
95% CI[c]	0.04, 0.77	
p-value[c]	0.0218	
QMG >= 16		
Subjects with rescue therapy - n / N1 (%)	20 / 52 (38.5)	8 / 55 (14.5)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	10.45, NA	NA, NA
Hazard ratio[c]	0.33	
95% CI[c]	0.15, 0.75	
p-value[c]	0.0085	
Treatment by baseline MGFA class interaction p-value[a]		0.6778
Baseline MGFA class		
II		

Subgroup	Placebo	Inebilizumab
Subjects with rescue therapy - n / N1 (%)	12 / 36 (33.3)	3 / 43 (7.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	11.37, NA	NA, NA
Hazard ratio[c]	0.25	
95% CI[c]	0.07, 0.89	
p-value[c]	0.0324	
III		
Subjects with rescue therapy - n / N1 (%)	14 / 49 (28.6)	7 / 49 (14.3)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	0.44	
95% CI[c]	0.18, 1.09	
p-value[c]	0.0769	
IV		
Subjects with rescue therapy - n / N1 (%)	6 / 7 (85.7)	1 / 3 (33.3)
Median time to first rescue therapy (months)[b]	4.60	NA
95% CI[b]	1.91, 7.49	1.22, NA
Hazard ratio[c]	0.54	
95% CI[c]	0.03, 9.47	
p-value[c]	0.6731	
Treatment by region interaction p-value[a]		0.3766
Region		
Asia		
Subjects with rescue therapy - n / N1 (%)	9 / 39 (23.1)	4 / 30 (13.3)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	0.50	
95% CI[c]	0.15, 1.63	
p-value[c]	0.2504	
Europe		
Subjects with rescue therapy - n / N1 (%)	16 / 39 (41.0)	3 / 37 (8.1)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	7.43, NA	NA, NA
Hazard ratio[c]	0.17	
95% CI[c]	0.05, 0.58	

Subgroup	Placebo	Inebilizumab
p-value[c]	0.0047	
North America		
Subjects with rescue therapy - n / N1 (%)	4 / 12 (33.3)	3 / 19 (15.8)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	2.40, NA	NA, NA
Hazard ratio[c]	0.44	
95% CI[c]	0.09, 2.05	
p-value[c]	0.2948	
Rest of the world		
Subjects with rescue therapy - n / N1 (%)	3 / 3 (100.0)	1 / 9 (11.1)
Median time to first rescue therapy (months)[b]	5.52	NA
95% CI[b]	1.58, NA	1.22, NA
Hazard ratio[c]	0.00	
95% CI[c]	0.00, NA	
p-value[c]	0.9972	
Treatment by region interaction p-value[a]		0.2110
Region		
EU		
Subjects with rescue therapy - n / N1 (%)	16 / 39 (41.0)	3 / 37 (8.1)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	7.43, NA	NA, NA
Hazard ratio[c]	0.17	
95% CI[c]	0.05, 0.58	
p-value[c]	0.0047	
Non-EU		
Subjects with rescue therapy - n / N1 (%)	16 / 54 (29.6)	8 / 58 (13.8)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	0.44	
95% CI[c]	0.19, 1.04	
p-value[c]	0.0621	
Treatment by region interaction p-value[a]		NA
Region		
Japan		

Subgroup	Placebo	Inebilizumab
Subjects with rescue therapy - n / N1 (%)	1 / 1 (100.0)	0 / 1 (0.0)
Median time to first rescue therapy (months)[b]	1.91	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Non-Japan		
Subjects with rescue therapy - n / N1 (%)	31 / 92 (33.7)	11 / 94 (11.7)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
MuSK+ Population (Week 26)		
Treatment by age interaction p-value[a]		NA
Age		
>= 18 - < 65 years		
Subjects with rescue therapy - n / N1 (%)	4 / 22 (18.2)	1 / 21 (4.8)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
>= 65 years		
Subjects with rescue therapy - n / N1 (%)	2 / 2 (100.0)	0 / 3 (0.0)
Median time to first rescue therapy (months)[b]	4.48	NA
95% CI[b]	4.11, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by sex interaction p-value[a]		NA
Sex		
Male		
Subjects with rescue therapy - n / N1 (%)	3 / 7 (42.9)	0 / 5 (0.0)

Subgroup	Placebo	Inebilizumab
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	1.61, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Female		
Subjects with rescue therapy - n / N1 (%)	3 / 17 (17.6)	1 / 19 (5.3)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by baseline steroid use interaction p-value[a]		NA
Baseline steroid use		
Prednisone <= 20 mg/day		
Subjects with rescue therapy - n / N1 (%)	2 / 13 (15.4)	1 / 19 (5.3)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Prednisone > 20 mg/day		
Subjects with rescue therapy - n / N1 (%)	4 / 10 (40.0)	0 / 2 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	1.02, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by baseline QMG interaction p-value[a]		NA
Baseline QMG		
QMG <= 15		
Subjects with rescue therapy - n / N1 (%)	2 / 9 (22.2)	0 / 13 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	1.02, NA	NA, NA

Subgroup	Placebo	Inebilizumab
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
QMG >= 16		
Subjects with rescue therapy - n / N1 (%)	4 / 15 (26.7)	0 / 9 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	3.81, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by baseline MGFA class interaction p-value[a]		NA
Baseline MGFA class		
II		
Subjects with rescue therapy - n / N1 (%)	4 / 12 (33.3)	0 / 13 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	2.79, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
III		
Subjects with rescue therapy - n / N1 (%)	2 / 12 (16.7)	1 / 9 (11.1)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	4.11, NA	1.64, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
IV		
Subjects with rescue therapy - n / N1 (%)	0 / 0 (-)	0 / 1 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by region interaction p-value[a]		NA

Subgroup	Placebo	Inebilizumab
Region		
Asia		
Subjects with rescue therapy - n / N1 (%)	4 / 15 (26.7)	0 / 14 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	3.81, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Europe		
Subjects with rescue therapy - n / N1 (%)	0 / 2 (0.0)	1 / 7 (14.3)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	1.64, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
North America		
Subjects with rescue therapy - n / N1 (%)	0 / 2 (0.0)	0 / 2 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Rest of the world		
Subjects with rescue therapy - n / N1 (%)	2 / 5 (40.0)	0 / 1 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	1.02, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by region interaction p-value[a]		NA
Region		
EU		
Subjects with rescue therapy - n / N1 (%)	0 / 2 (0.0)	1 / 7 (14.3)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	1.64, NA

Subgroup	Placebo	Inebilizumab
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Non-EU		
Subjects with rescue therapy - n / N1 (%)	6 / 22 (27.3)	0 / 17 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	4.86, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Treatment by region interaction p-value[a]		NA
Region		
Japan		
Subjects with rescue therapy - n / N1 (%)	1 / 2 (50.0)	0 / 2 (0.0)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	2.79, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	
Non-Japan		
Subjects with rescue therapy - n / N1 (%)	5 / 22 (22.7)	1 / 22 (4.5)
Median time to first rescue therapy (months)[b]	NA	NA
95% CI[b]	NA, NA	NA, NA
Hazard ratio[c]	NA	
95% CI[c]	NA, NA	
p-value[c]	NA	

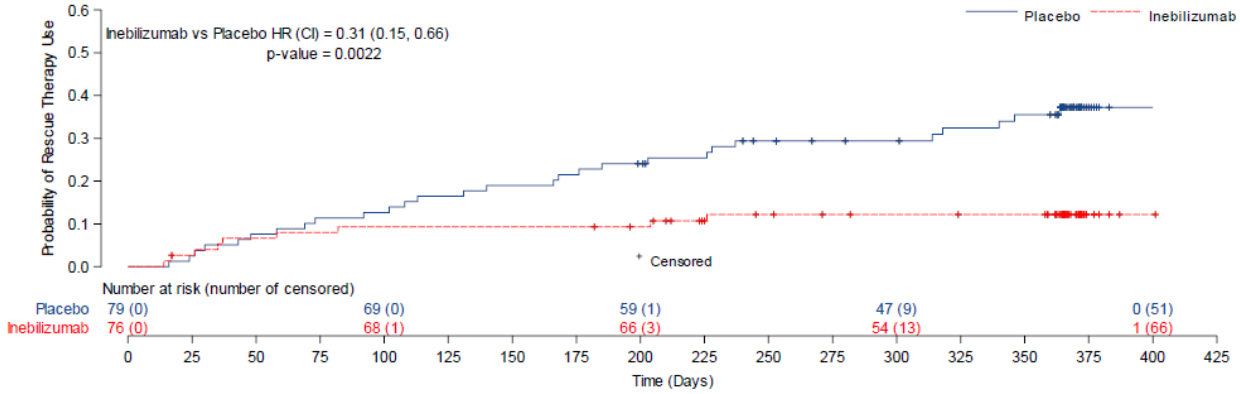
Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. CI = Confidence interval.
To convert days to months: 1 month = 30.4375 days. An exacerbation is defined as Use of protocol defined rescue therapy, or Myasthenic crisis or Significant symptomatic worsening.
[a] Based on Cox regression method, with common covariates of treatment group, baseline steroid use status (daily prednisone dose <= 5 mg vs daily prednisone dose > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), baseline MG-ADL score, subgroup variable, and treatment × subgroup variable.
[b] Based on Kaplan-Meier method.

Subgroup	Placebo	Inebilizumab
[c] Based on Cox regression method, with common covariates of treatment group, baseline steroid use status (daily prednisone dose <= 5 mg vs daily prednisone dose > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score.		

1.6.3 Kaplan-Meier-Kurven: Zeit bis zur ersten Rescue-Therapie (Treatment-policy Strategie)

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

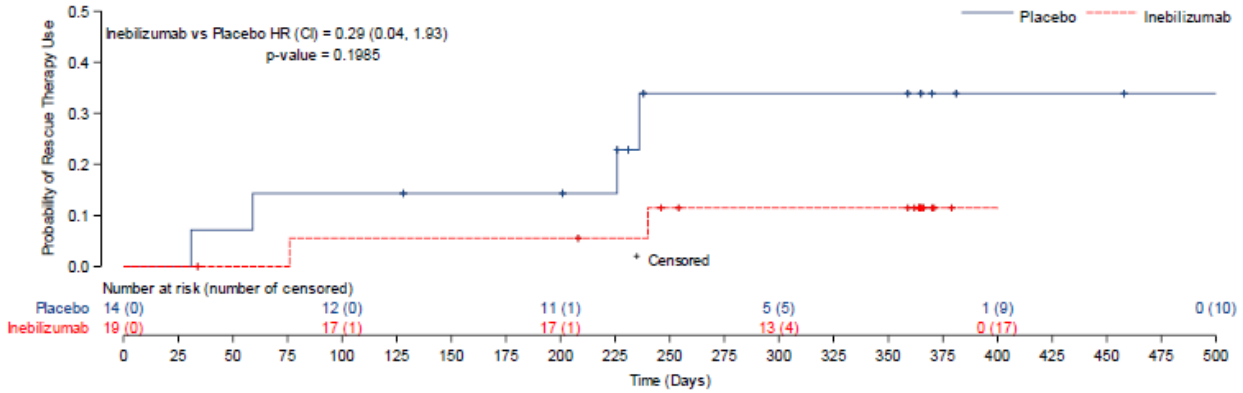
Subgroup = Age >= 18 - < 65 years



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

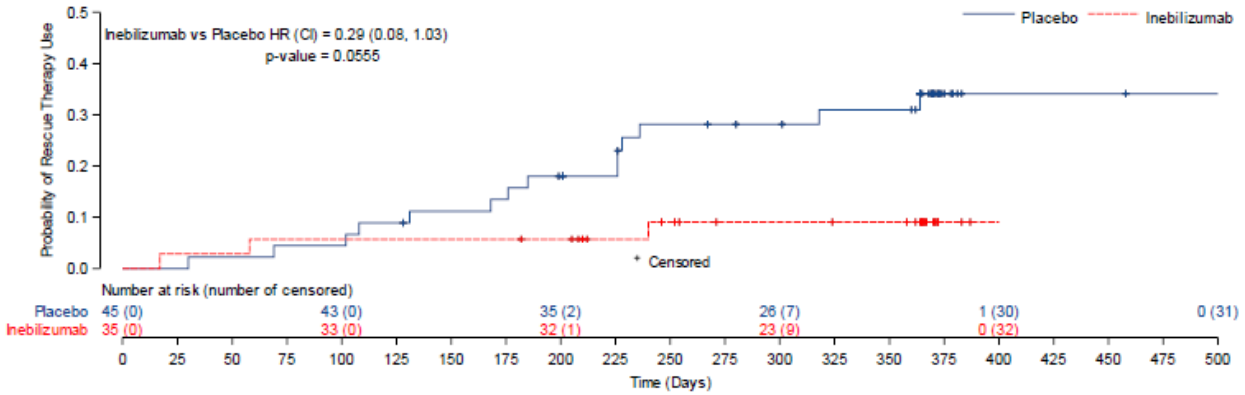
Subgroup = Age >= 65 years



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

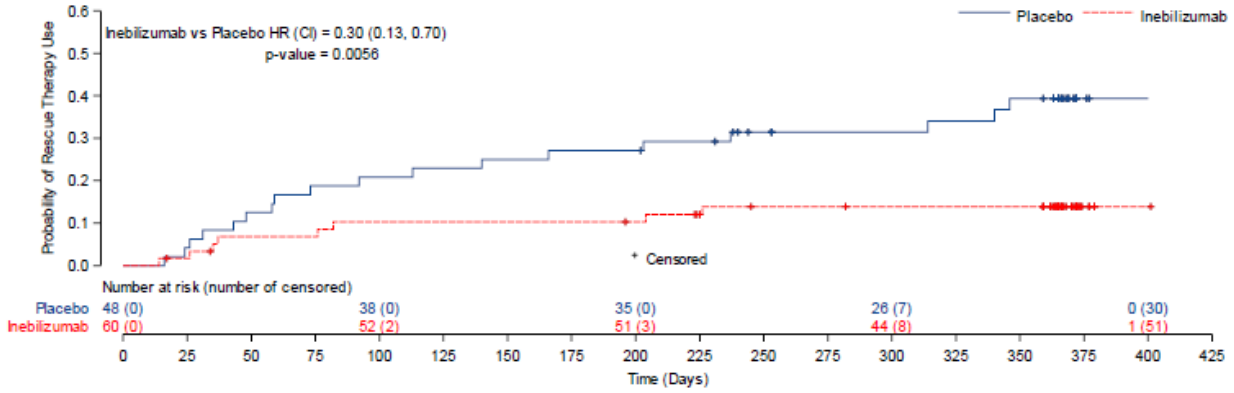
Subgroup = Sex Male



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

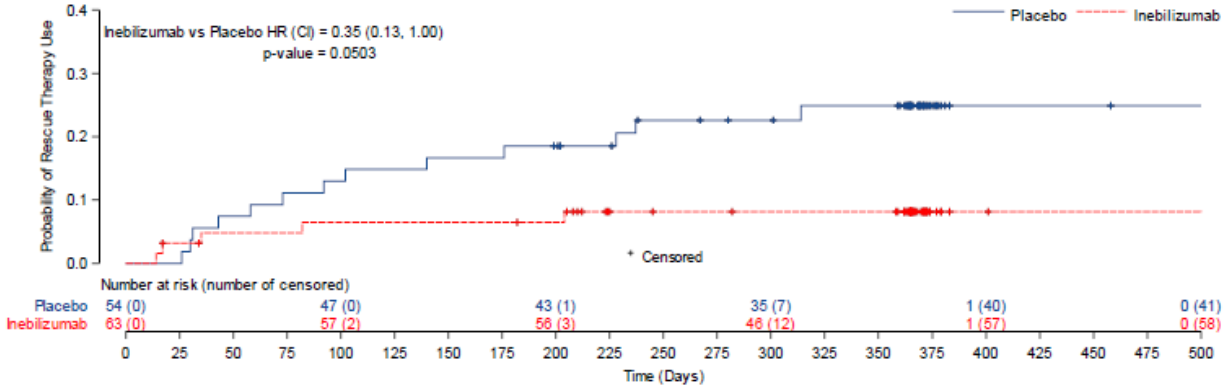
Subgroup = Sex Female



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

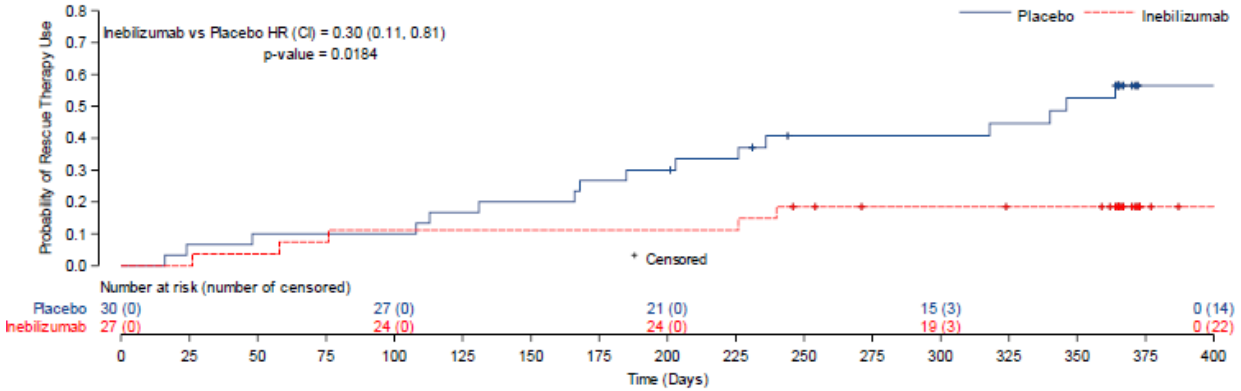
Subgroup = Baseline steroid use Prednisone <= 20 mg/day



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

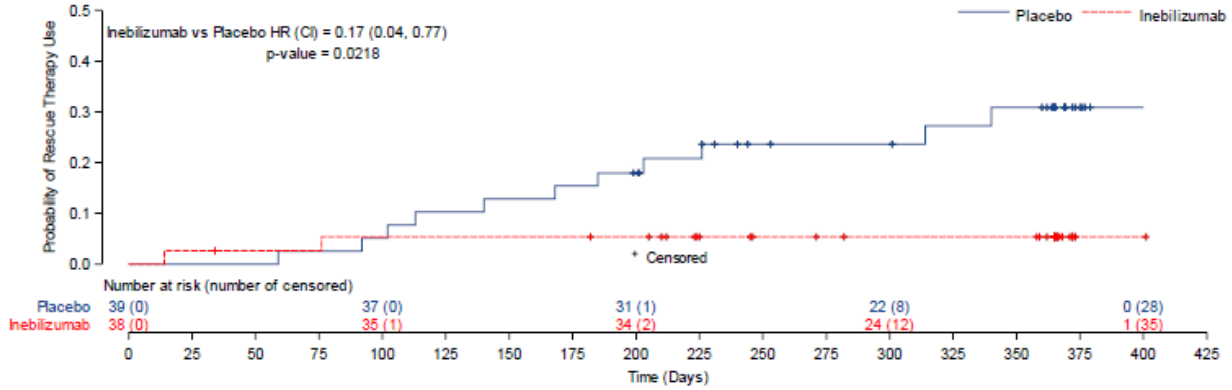
Subgroup = Baseline steroid use Prednisone > 20 mg/day



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

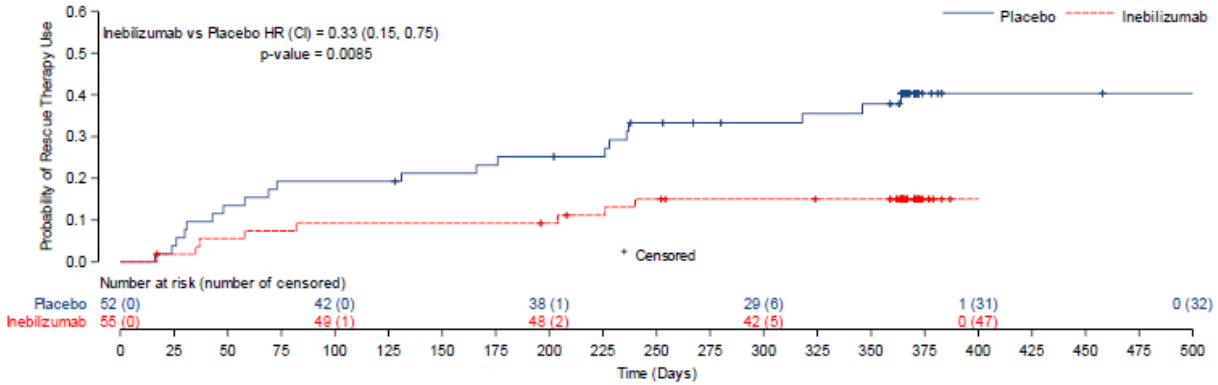
Subgroup = Baseline QMG QMG <= 15



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

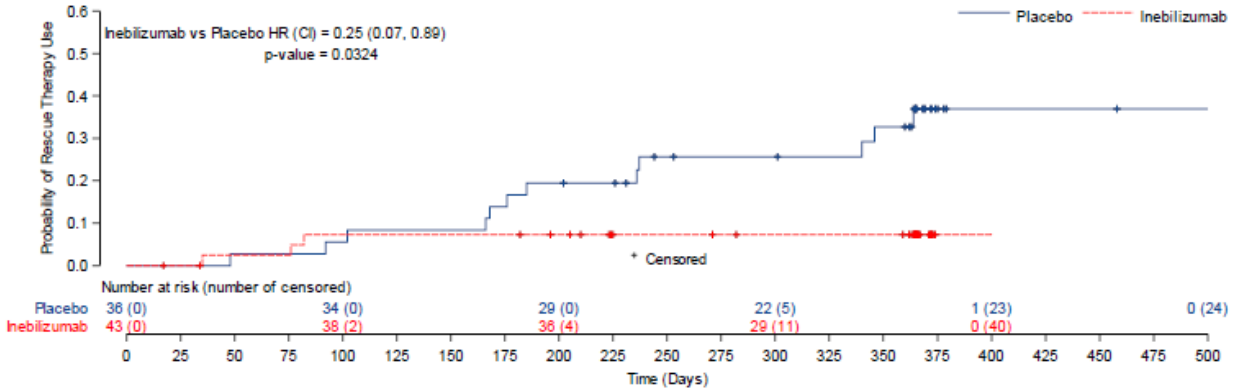
Subgroup = Baseline QMG QMG >= 16



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

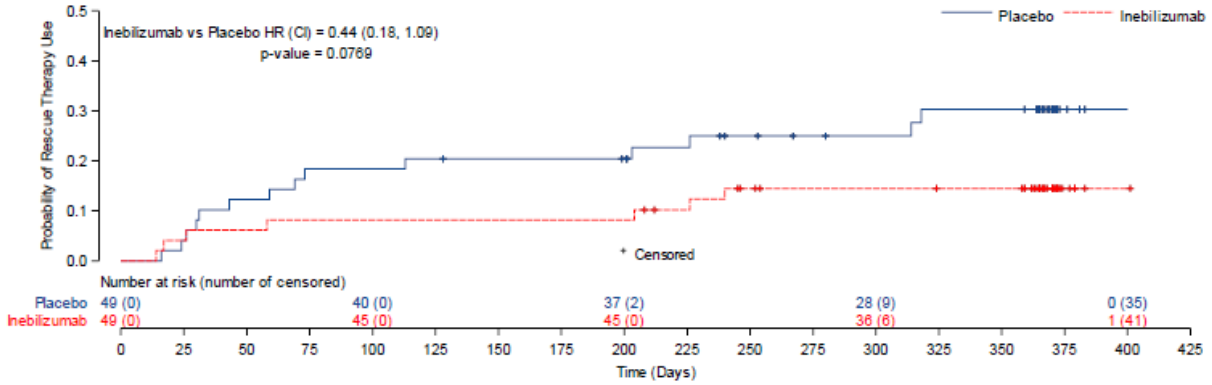
Subgroup = Baseline MGFA class II



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

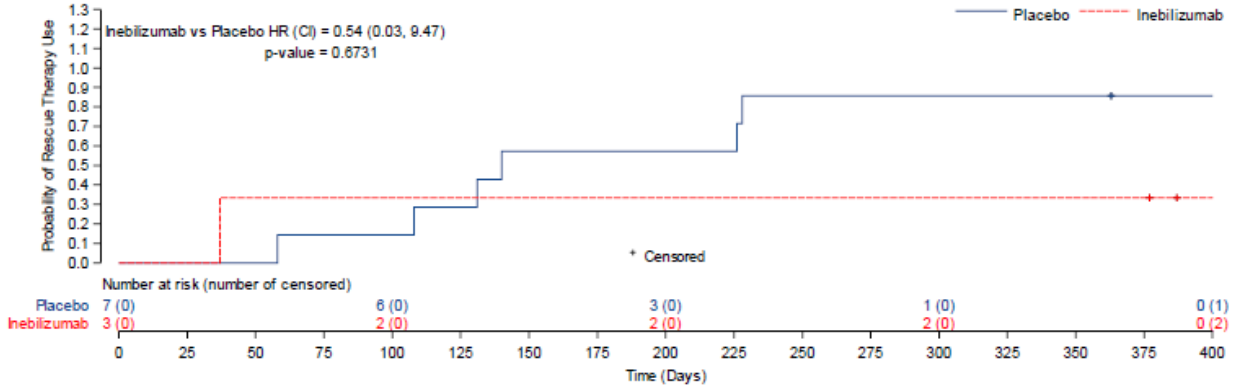
Subgroup = Baseline MGFA class III



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

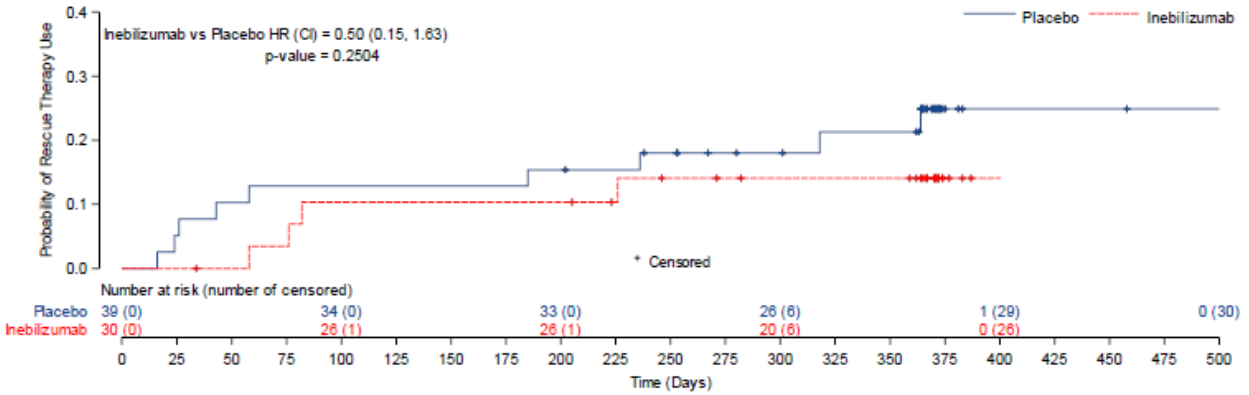
Subgroup = Baseline MGFA class IV



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

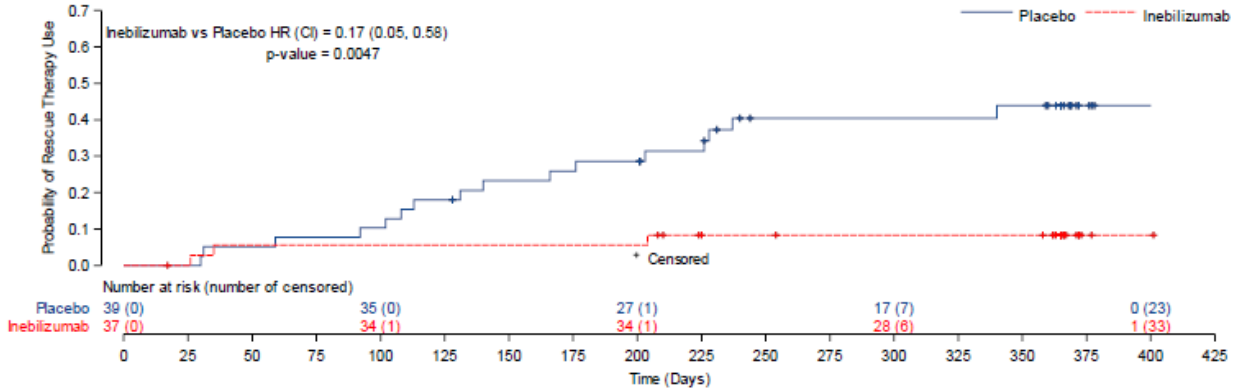
Subgroup = Region Asia



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

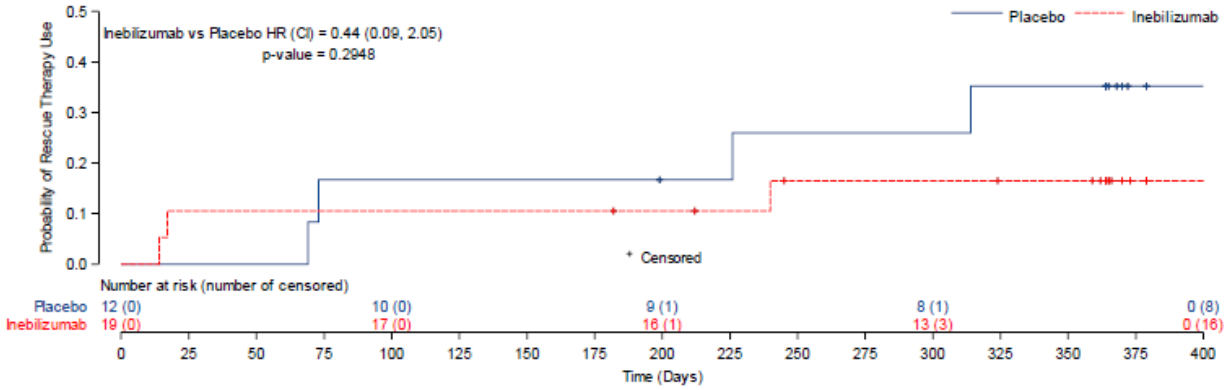
Subgroup = Region Europe



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

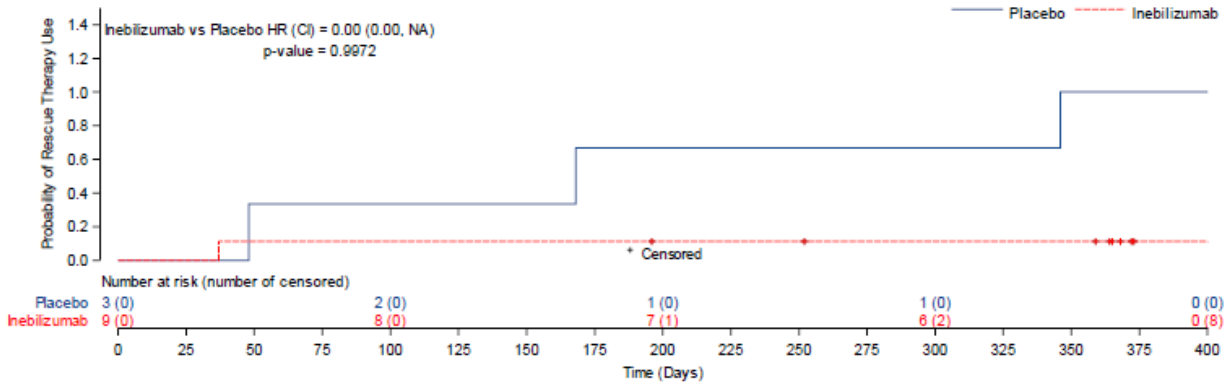
Subgroup = Region North America



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

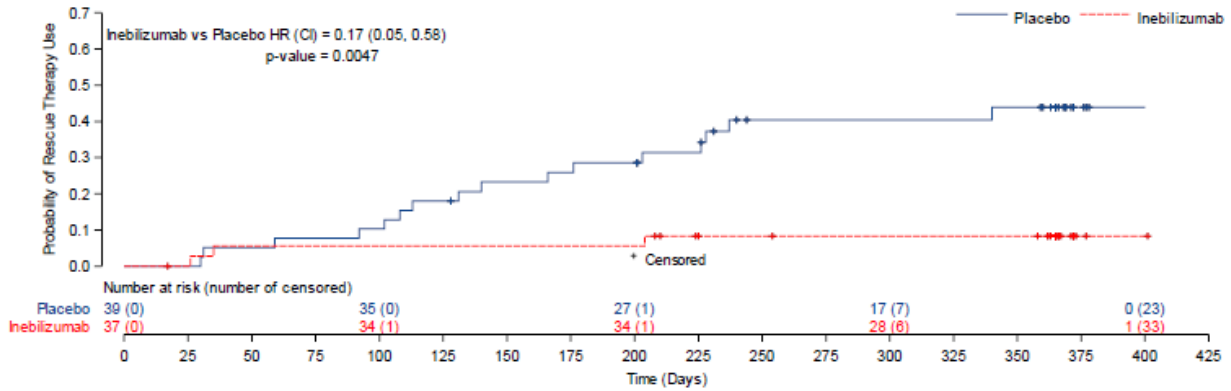
Subgroup = Region Rest of the world



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

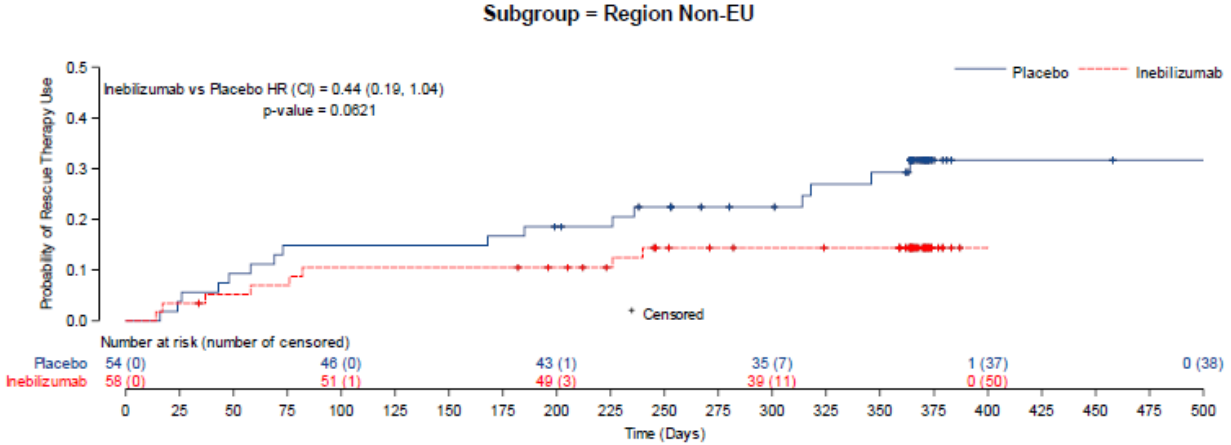
Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

Subgroup = Region EU



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

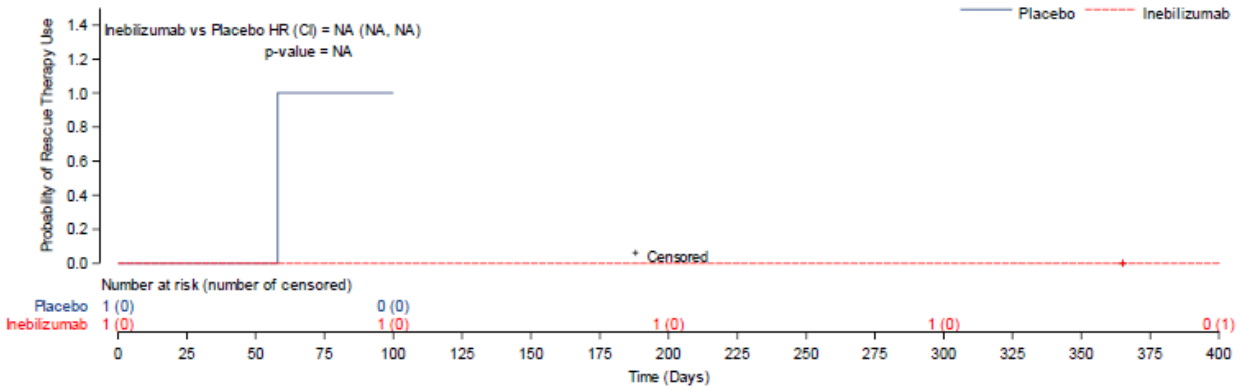
Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

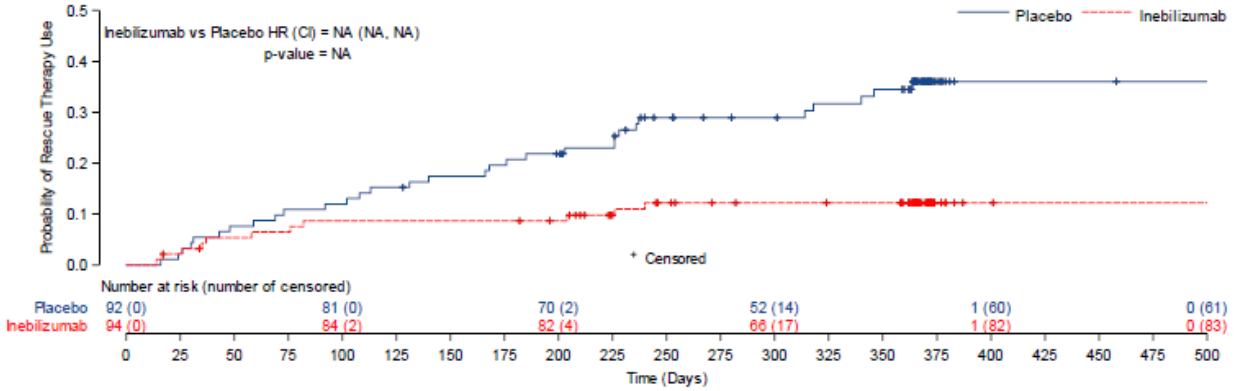
Subgroup = Region Japan



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.584. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 52 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: AChR+ Population)

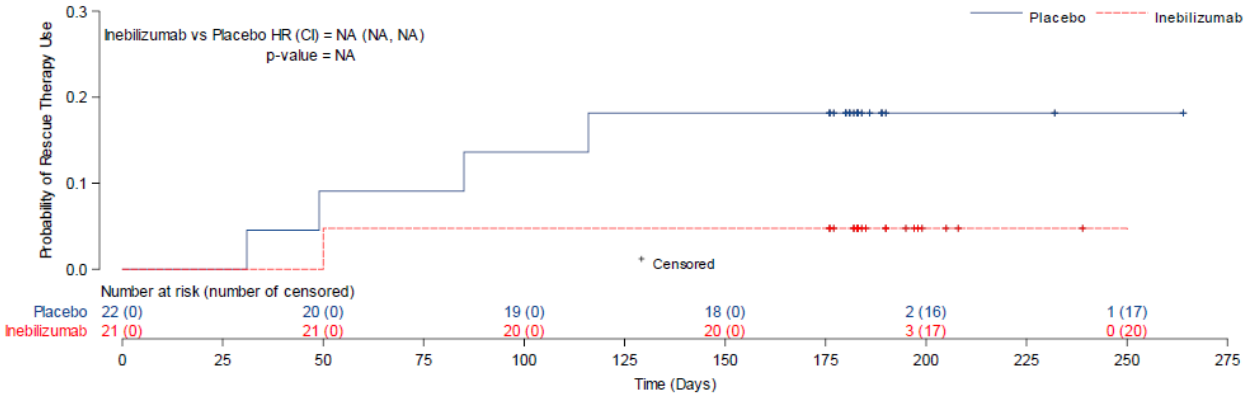
Subgroup = Region Non-Japan



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

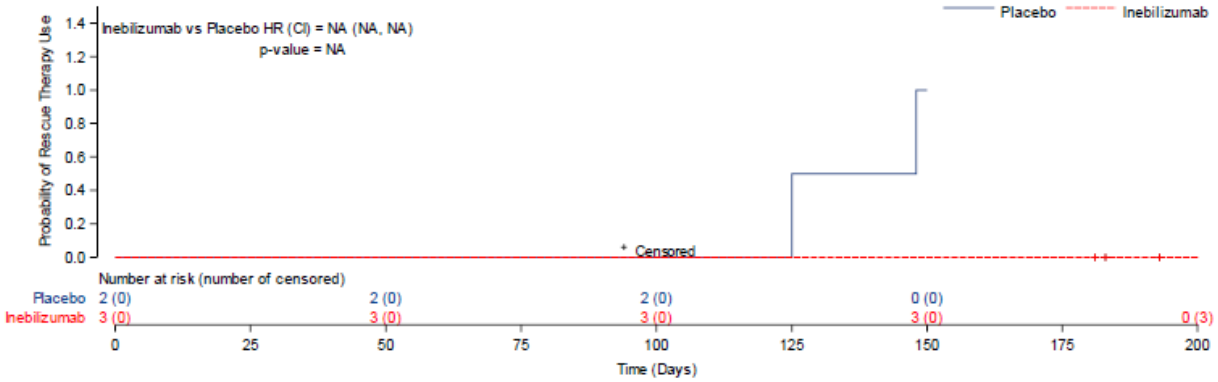
Subgroup = Age >= 18 - < 65 years



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

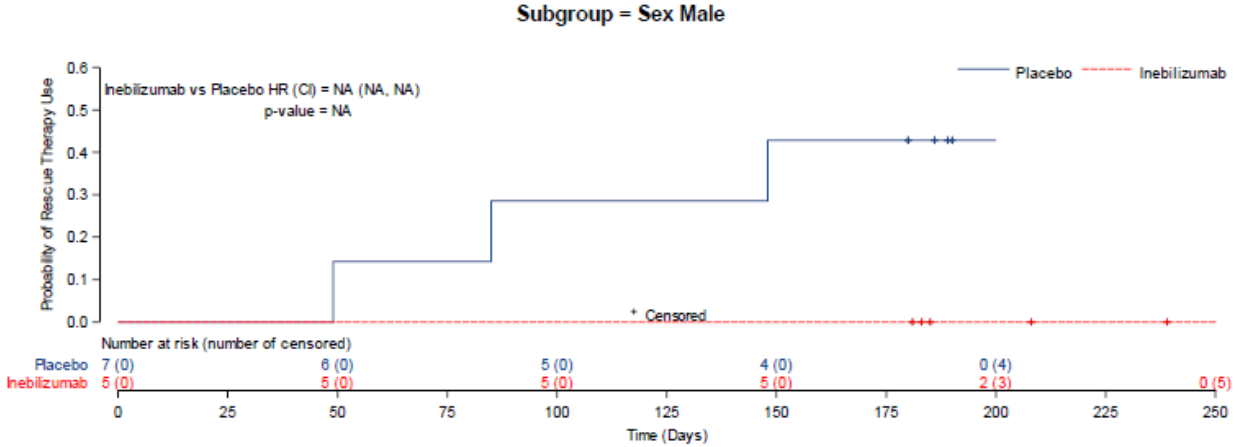
Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

Subgroup = Age >= 65 years



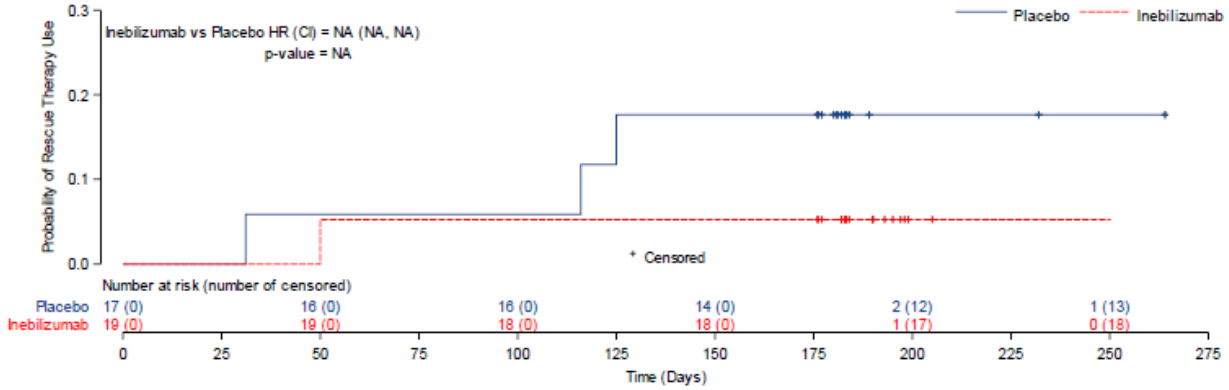
Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

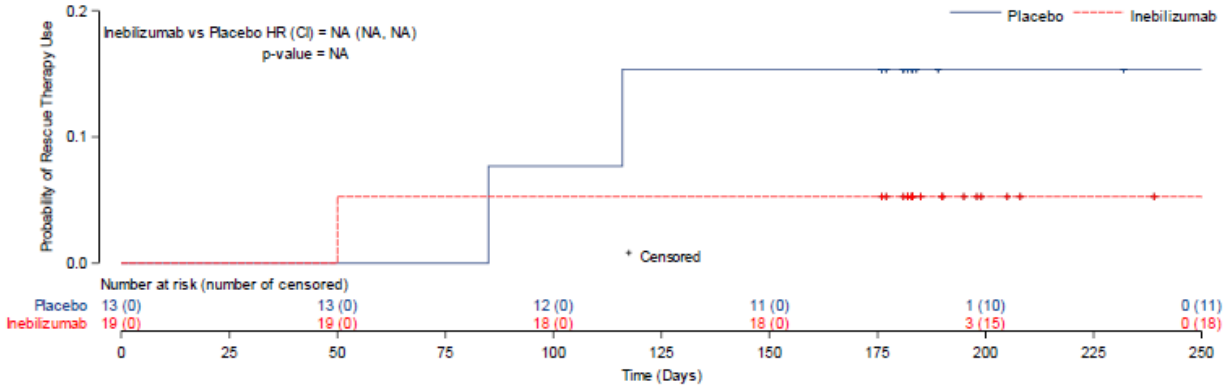
Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

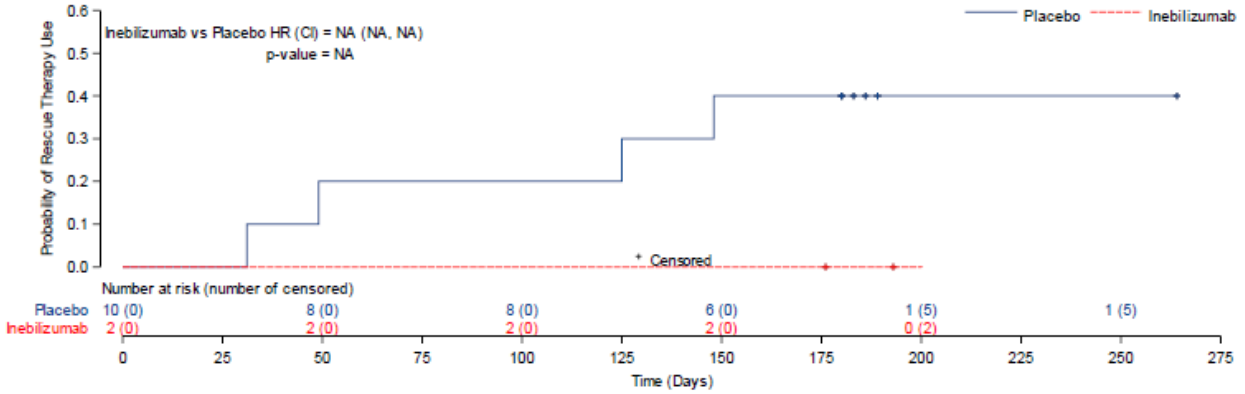
Subgroup = Baseline steroid use Prednisone <= 20 mg/day



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

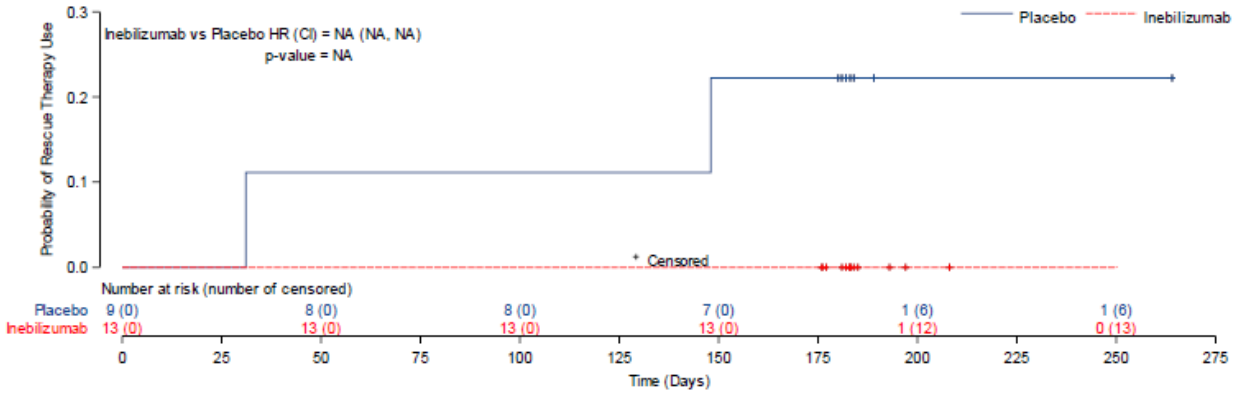
Subgroup = Baseline steroid use Prednisone > 20 mg/day



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

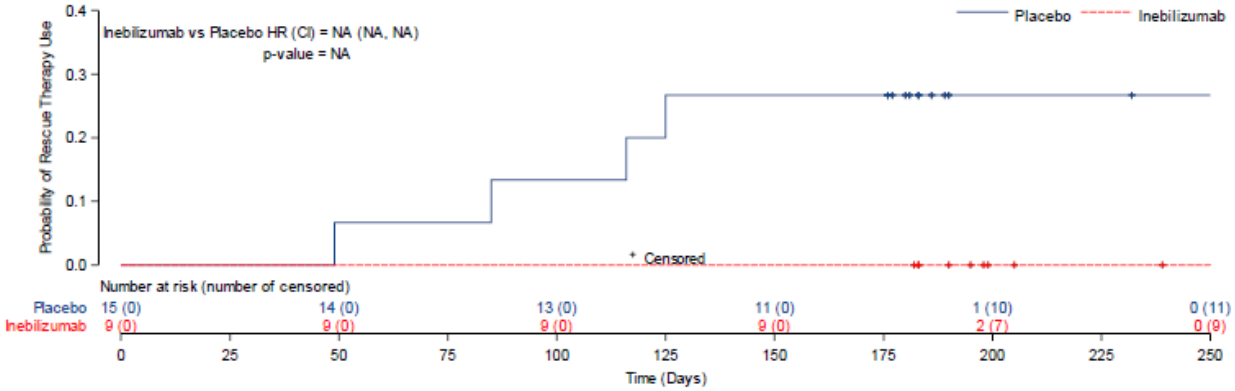
Subgroup = Baseline QMG QMG <= 15



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

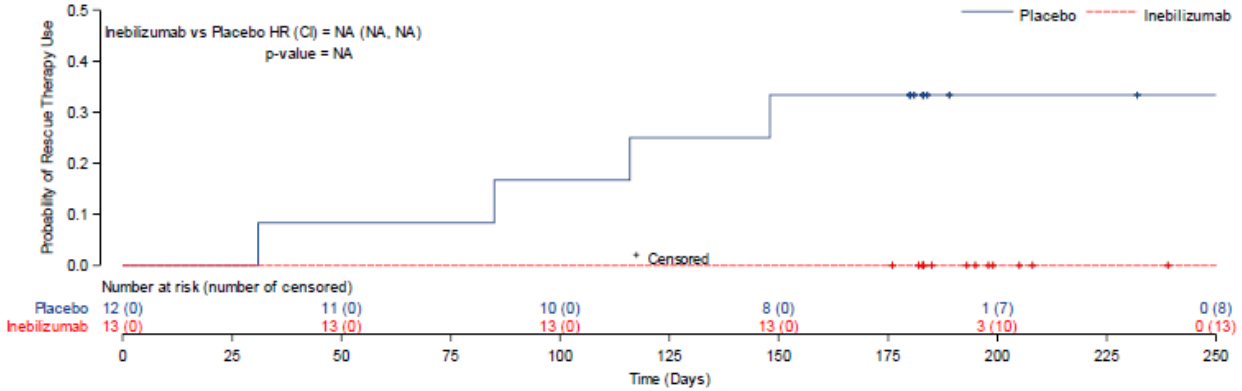
Subgroup = Baseline QMG QMG >= 16



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

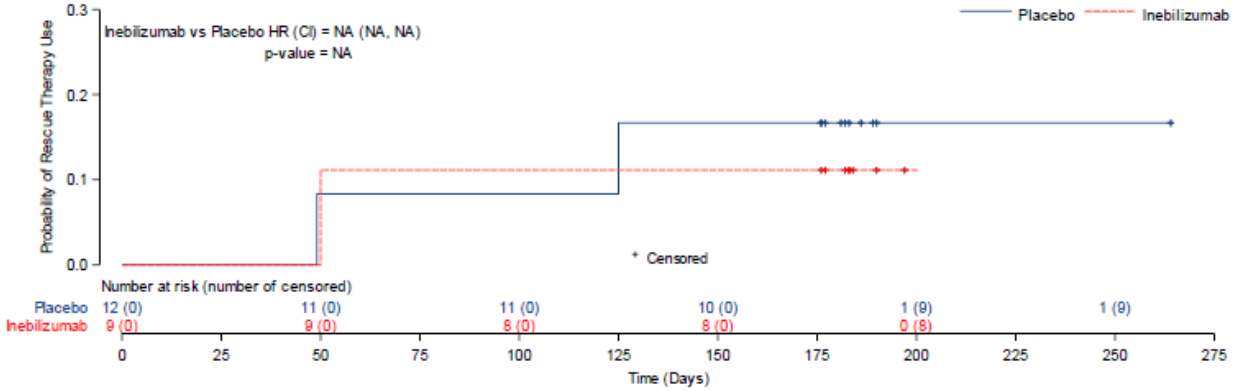
Subgroup = Baseline MGFA class II



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

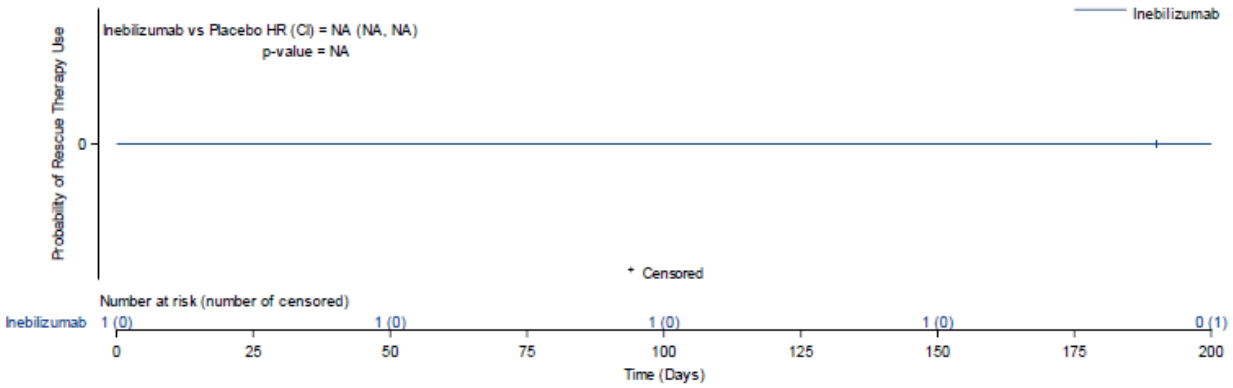
Subgroup = Baseline MGFA class III



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

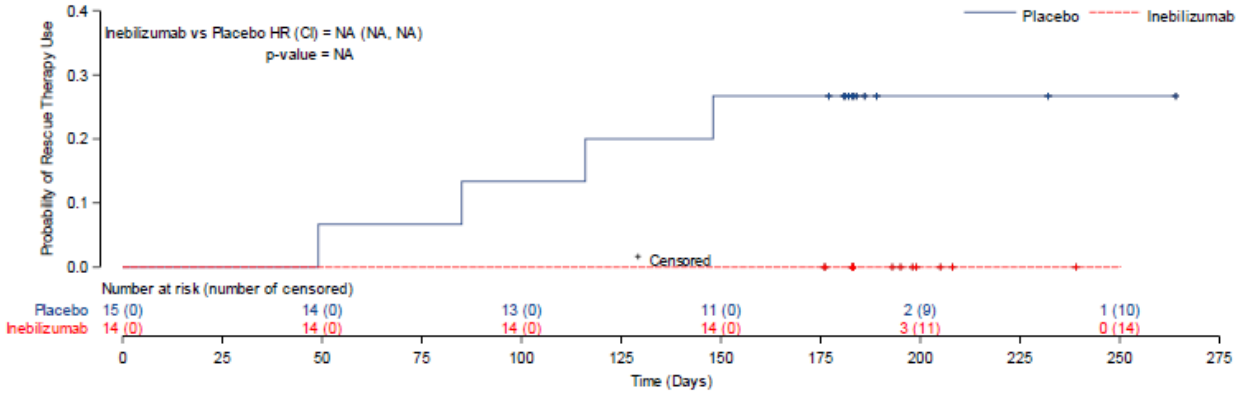
Subgroup = Baseline MGFA class IV



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

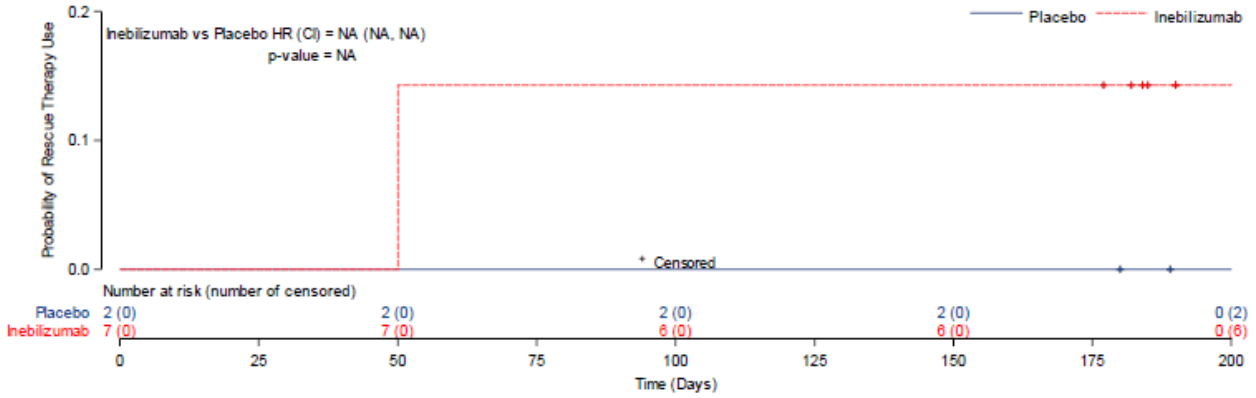
Subgroup = Region Asia



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

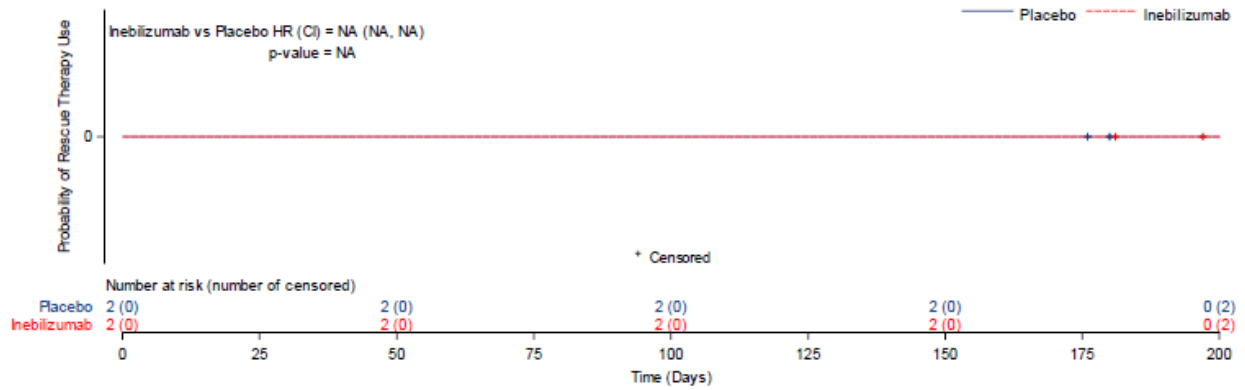
Subgroup = Region Europe



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

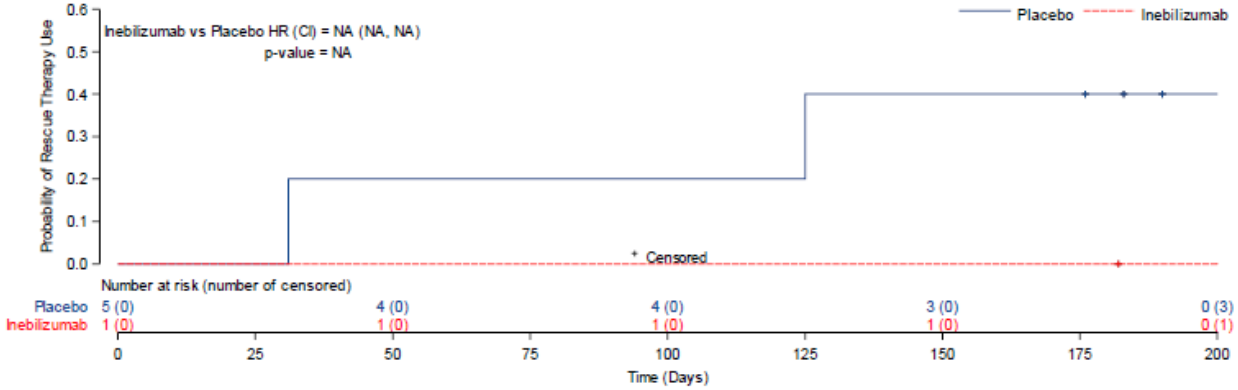
Subgroup = Region North America



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

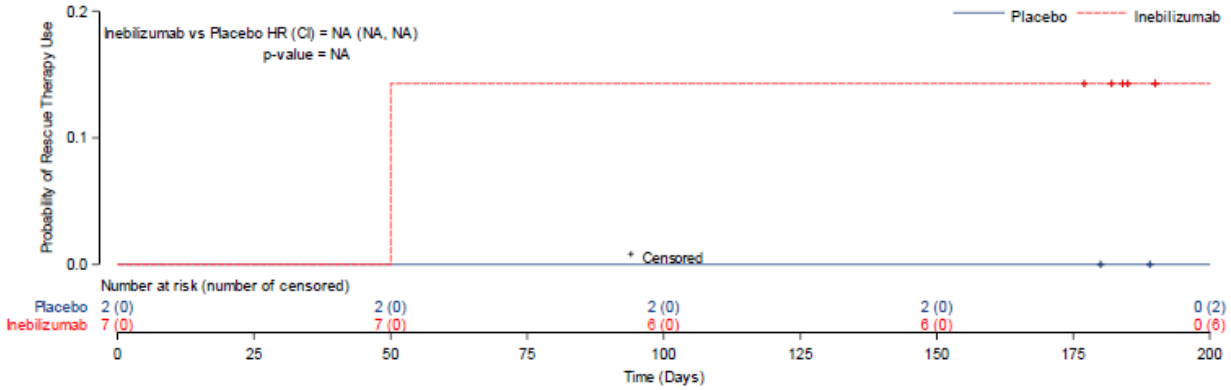
Subgroup = Region Rest of the world



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

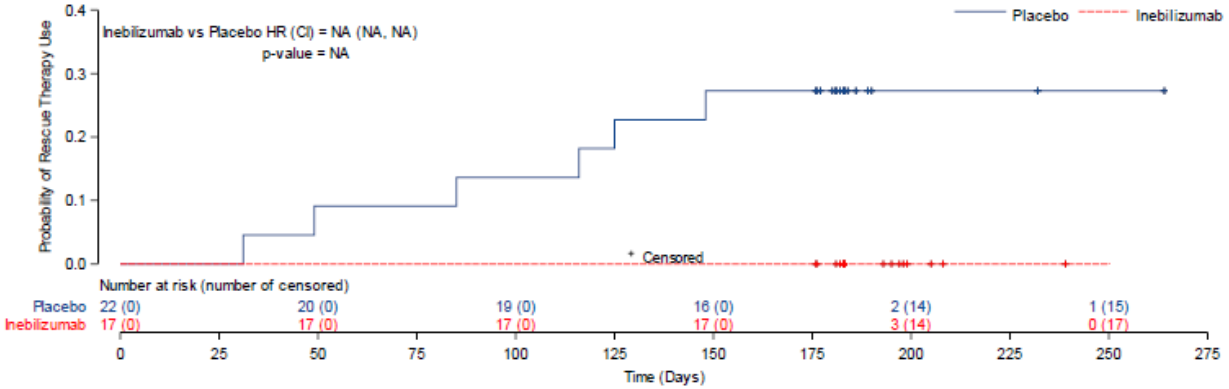
Subgroup = Region EU



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

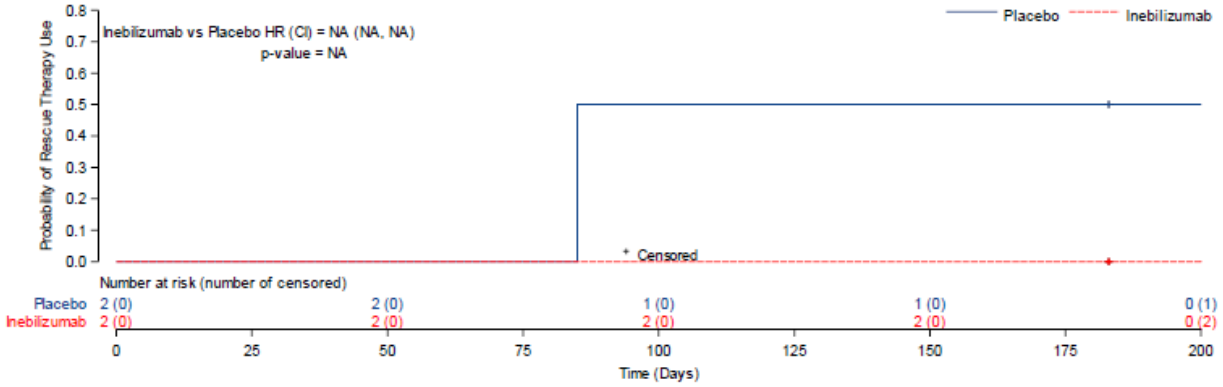
Subgroup = Region Non-EU



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

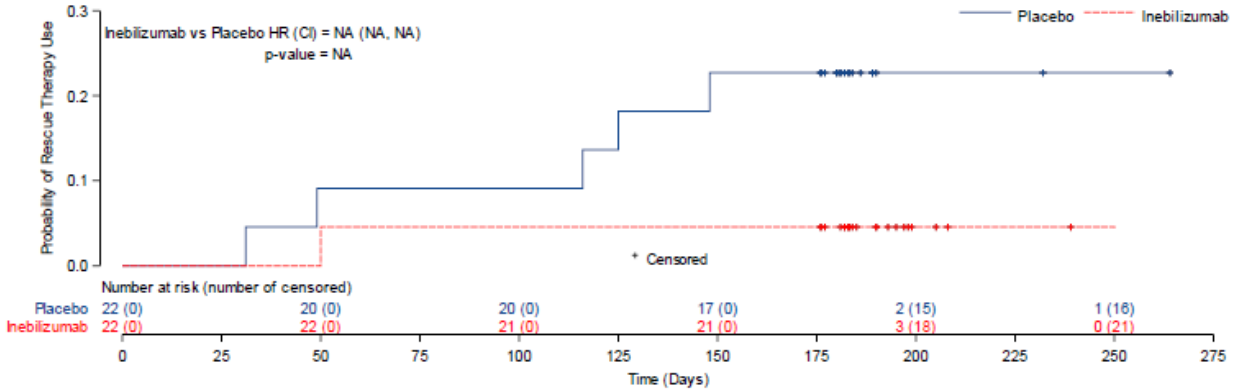
Subgroup = Region Japan



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

Figure 14-2.7.3.2.583. Subgroup Analysis: Kaplan Meier Plot for Time to First Rescue Therapy Use Using Treatment-policy Strategy by Week 26 Using Treatment-policy Strategy During Randomized Controlled Period (Full Analysis Set: MuSK+ Population)

Subgroup = Region Non-Japan



Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.

1.7 Steroid-Reduktion

1.7.1 Anteil an Patientinnen und Patienten mit einer Steroid-Reduktion auf ≤ 5 mg bei einer Steroid-Dosis von > 5 mg zur Baseline

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									0.4721
>= 18 - < 65 years	50 / 54 (92.6)	51 / 55 (92.7)	0.90 (0.23, 3.49)	0.8746	1.00 (0.88, 1.14)	1.0000	-0.39 (-5.17, 4.39)	0.8738	
>= 65 years	6 / 6 (100.0)	9 / 11 (81.8)	0.30 (0.01, 8.64)	0.4813	0.85 (0.54, 1.47)	0.5147	-15.26 (-50.14, 19.62)	0.3912	
Sex									1.0000
Male	26 / 29 (89.7)	17 / 21 (81.0)	0.58 (0.12, 2.75)	0.4963	0.90 (0.66, 1.15)	0.4341	-6.90 (-27.21, 13.41)	0.5056	
Female	30 / 31 (96.8)	43 / 45 (95.6)	0.78 (0.12, 5.12)	0.7935	0.99 (0.88, 1.15)	1.0000	-1.12 (-9.35, 7.11)	0.7892	
Baseline steroid use									0.5165
Prednisone <= 20 mg/day	36 / 37 (97.3)	41 / 45 (91.1)	0.40 (0.07, 2.29)	0.3013	0.94 (0.81, 1.07)	0.3717	-5.42 (-16.97, 6.14)	0.3584	
Prednisone > 20 mg/day	20 / 23 (87.0)	19 / 21 (90.5)	1.11 (0.20, 6.36)	0.9032	1.04 (0.80, 1.36)	1.0000	1.17 (-18.15, 20.49)	0.9055	
Baseline QMG									NA
QMG <= 15	23 / 23 (100.0)	25 / 25 (100.0)	NA	NA	NA	NA	NA	NA	
QMG >= 16	31 / 35 (88.6)	34 / 39 (87.2)	0.75 (0.19, 2.97)	0.6815	0.98 (0.81, 1.20)	1.0000	-2.64 (-15.13, 9.85)	0.6789	
Baseline MGFA class									NA
II	21 / 23 (91.3)	24 / 26 (92.3)	NA	NA	NA	NA	NA	NA	
III	30 / 32 (93.8)	34 / 38 (89.5)	NA	NA	NA	NA	NA	NA	
IV	4 / 4 (100.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	23 / 26 (88.5)	18 / 20 (90.0)	NA	NA	NA	NA	NA	NA	
Europe	26 / 27 (96.3)	29 / 30 (96.7)	NA	NA	NA	NA	NA	NA	
North America	5 / 5 (100.0)	8 / 11 (72.7)	NA	NA	NA	NA	NA	NA	
Rest of the world	2 / 2 (100.0)	5 / 5 (100.0)	NA	NA	NA	NA	NA	NA	
Region									1.0000

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
EU	26 / 27 (96.3)	29 / 30 (96.7)	0.92 (0.10, 8.68)	0.9455	1.00 (0.86, 1.19)	1.0000	-0.21 (-6.32, 5.90)	0.9455	
Non-EU	30 / 33 (90.9)	31 / 36 (86.1)	0.57 (0.14, 2.37)	0.4409	0.95 (0.77, 1.15)	0.7117	-5.30 (-18.89, 8.30)	0.4453	
Region									NA
Japan	0 / 0 (-)	0 / 0 (-)	NA	NA	NA	NA	NA	NA	
Non-Japan	56 / 60 (93.3)	60 / 66 (90.9)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	12 / 17 (70.6)	14 / 15 (93.3)	NA	NA	NA	NA	NA	NA	
>= 65 years	1 / 2 (50.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Sex									0.9138
Male	4 / 6 (66.7)	5 / 5 (100.0)	7.28 (0.14, 379.72)	0.3251	1.43 (0.72, 3.09)	0.4545	28.93 (-21.34, 79.21)	0.2594	
Female	9 / 13 (69.2)	11 / 12 (91.7)	2.98 (0.35, 25.29)	0.3162	1.32 (0.87, 2.20)	0.3217	15.79 (-14.10, 45.67)	0.3006	
Baseline steroid use									0.9454
Prednisone <= 20 mg/day	7 / 9 (77.8)	14 / 15 (93.3)	3.33 (0.32, 34.97)	0.3153	1.20 (0.85, 2.08)	0.5331	12.58 (-14.30, 39.47)	0.3591	
Prednisone > 20 mg/day	6 / 10 (60.0)	2 / 2 (100.0)	3.61 (0.06, 223.30)	0.5417	1.41 (0.49, 2.82)	0.5152	25.42 (-37.53, 88.38)	0.4286	
Baseline QMG									0.9203
QMG <= 15	5 / 7 (71.4)	9 / 9 (100.0)	3.97 (0.11, 138.37)	0.4470	1.38 (0.87, 2.69)	0.1750	13.92 (-22.28, 50.12)	0.4511	
QMG >= 16	8 / 12 (66.7)	6 / 6 (100.0)	5.12 (0.26, 100.07)	0.2817	1.42 (0.80, 2.43)	0.2451	25.64 (-10.40, 61.69)	0.1632	
Baseline MGFA class									NA
II	7 / 10 (70.0)	10 / 10 (100.0)	NA	NA	NA	NA	NA	NA	
III	6 / 9 (66.7)	4 / 5 (80.0)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
Asia	10 / 13 (76.9)	10 / 10 (100.0)	NA	NA	NA	NA	NA	NA	
Europe	2 / 2 (100.0)	4 / 5 (80.0)	NA	NA	NA	NA	NA	NA	
North America	1 / 1 (100.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	0 / 3 (0.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	2 / 2 (100.0)	4 / 5 (80.0)	NA	NA	NA	NA	NA	NA	
Non-EU	11 / 17 (64.7)	12 / 12 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	1 / 1 (100.0)	0 / 0 (-)	NA	NA	NA	NA	NA	NA	
Non-Japan	12 / 18 (66.7)	16 / 17 (94.1)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects who had baseline steroid > 5 mg/day and were ongoing at that visit in each subgroup level. CI = Confidence interval.
Baseline is defined as the last valid value on or prior to the 1st dose of Randomized controlled period.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.7.2 Anteil an Patientinnen und Patienten mit einer Steroid-Reduktion um ≥ 50 % bei einer Steroid-Dosis von > 5 mg zur Baseline

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	34 / 54 (63.0)	34 / 55 (61.8)	0.97 (0.44, 2.16)	0.9487	0.98 (0.73, 1.32)	1.0000	-0.64 (-20.26, 18.97)	0.9487	
>= 65 years	5 / 6 (83.3)	8 / 11 (72.7)	0.55 (0.05, 6.21)	0.6253	0.87 (0.50, 1.76)	1.0000	-11.26 (-53.49, 30.97)	0.6012	
Sex									0.4494
Male	17 / 29 (58.6)	14 / 21 (66.7)	1.41 (0.42, 4.67)	0.5781	1.14 (0.72, 1.76)	0.7685	8.05 (-19.99, 36.09)	0.5737	
Female	22 / 31 (71.0)	28 / 45 (62.2)	0.70 (0.25, 1.92)	0.4850	0.88 (0.63, 1.24)	0.4703	-8.67 (-32.58, 15.25)	0.4775	
Baseline steroid use									0.5791
Prednisone <= 20 mg/day	19 / 37 (51.4)	22 / 45 (48.9)	0.97 (0.39, 2.39)	0.9473	0.95 (0.62, 1.49)	1.0000	-0.74 (-22.72, 21.24)	0.9474	
Prednisone > 20 mg/day	20 / 23 (87.0)	20 / 21 (95.2)	1.93 (0.27, 13.70)	0.5127	1.10 (0.87, 1.41)	0.6086	7.57 (-19.79, 34.92)	0.5877	
Baseline QMG									1.0000
QMG <= 15	13 / 23 (56.5)	14 / 25 (56.0)	1.19 (0.36, 3.93)	0.7783	0.99 (0.60, 1.66)	1.0000	3.59 (-21.31, 28.50)	0.7773	
QMG >= 16	24 / 35 (68.6)	26 / 39 (66.7)	0.86 (0.32, 2.28)	0.7609	0.97 (0.70, 1.36)	1.0000	-2.39 (-17.77, 12.99)	0.7605	
Baseline MGFA class									NA
II	12 / 23 (52.2)	15 / 26 (57.7)	NA	NA	NA	NA	NA	NA	
III	23 / 32 (71.9)	25 / 38 (65.8)	NA	NA	NA	NA	NA	NA	
IV	4 / 4 (100.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	16 / 26 (61.5)	13 / 20 (65.0)	NA	NA	NA	NA	NA	NA	
Europe	17 / 27 (63.0)	20 / 30 (66.7)	NA	NA	NA	NA	NA	NA	
North America	4 / 5 (80.0)	7 / 11 (63.6)	NA	NA	NA	NA	NA	NA	

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
Rest of the world	2 / 2 (100.0)	2 / 5 (40.0)	NA	NA	NA	NA	NA	NA	
Region									0.7121
EU	17 / 27 (63.0)	20 / 30 (66.7)	1.29 (0.42, 3.96)	0.6529	1.06 (0.72, 1.60)	0.7885	6.17 (-20.71, 33.06)	0.6527	
Non-EU	22 / 33 (66.7)	22 / 36 (61.1)	0.83 (0.30, 2.31)	0.7156	0.92 (0.63, 1.32)	0.8024	-4.69 (-29.71, 20.33)	0.7135	
Region									NA
Japan	0 / 0 (-)	0 / 0 (-)	NA	NA	NA	NA	NA	NA	
Non-Japan	39 / 60 (65.0)	42 / 66 (63.6)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	11 / 17 (64.7)	8 / 15 (53.3)	NA	NA	NA	NA	NA	NA	
>= 65 years	1 / 2 (50.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Sex									1.0000
Male	4 / 6 (66.7)	3 / 5 (60.0)	1.08 (0.05, 22.48)	0.9597	0.90 (0.32, 2.32)	1.0000	1.79 (-67.57, 71.16)	0.9596	
Female	8 / 13 (61.5)	7 / 12 (58.3)	0.65 (0.11, 3.78)	0.6318	0.95 (0.47, 1.84)	1.0000	-10.08 (-51.02, 30.87)	0.6296	
Baseline steroid use									0.6136
Prednisone <= 20 mg/day	5 / 9 (55.6)	8 / 15 (53.3)	0.95 (0.18, 5.09)	0.9546	0.96 (0.46, 2.21)	1.0000	-1.21 (-42.85, 40.43)	0.9546	
Prednisone > 20 mg/day	7 / 10 (70.0)	2 / 2 (100.0)	2.82 (0.04, 187.84)	0.6282	1.22 (0.43, 2.27)	1.0000	18.16 (-40.51, 76.83)	0.5440	
Baseline QMG									1.0000
QMG <= 15	5 / 7 (71.4)	6 / 9 (66.7)	0.27 (0.02, 3.95)	0.3375	0.93 (0.46, 2.02)	1.0000	-25.76 (-74.08, 22.56)	0.2961	
QMG >= 16	7 / 12 (58.3)	3 / 6 (50.0)	0.74 (0.10, 5.33)	0.7638	0.86 (0.30, 1.96)	1.0000	-7.52 (-56.57, 41.53)	0.7638	
Baseline MGFA class									NA
II	5 / 10 (50.0)	5 / 10 (50.0)	NA	NA	NA	NA	NA	NA	
III	7 / 9 (77.8)	4 / 5 (80.0)	NA	NA	NA	NA	NA	NA	

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
IV	0 / 0 (-)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	8 / 13 (61.5)	7 / 10 (70.0)	NA	NA	NA	NA	NA	NA	
Europe	2 / 2 (100.0)	2 / 5 (40.0)	NA	NA	NA	NA	NA	NA	
North America	1 / 1 (100.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	1 / 3 (33.3)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	2 / 2 (100.0)	2 / 5 (40.0)	NA	NA	NA	NA	NA	NA	
Non-EU	10 / 17 (58.8)	8 / 12 (66.7)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	1 / 1 (100.0)	0 / 0 (-)	NA	NA	NA	NA	NA	NA	
Non-Japan	11 / 18 (61.1)	10 / 17 (58.8)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log. MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects who had baseline steroid > 5 mg/day and were ongoing at that visit in each subgroup level. CI = Confidence interval. Baseline is defined as the last valid value on or prior to the 1st dose of Randomized controlled period.

[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score as common covariates. 95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios. If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.8 Hospitalisierung

1.8.1 Hospitalisierung (Treatment-policy Strategie)

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	30 / 79 (38.0)	13 / 76 (17.1)	- No data to report -						
>= 65 years	3 / 14 (21.4)	2 / 19 (10.5)							
Sex									0.7204
Male	15 / 45 (33.3)	6 / 35 (17.1)	- No data to report -						
Female	18 / 48 (37.5)	9 / 60 (15.0)							
Baseline steroid use									0.4448
Prednisone <= 20 mg/day	17 / 54 (31.5)	10 / 63 (15.9)	- No data to report -						
Prednisone > 20 mg/day	15 / 30 (50.0)	4 / 27 (14.8)							
Baseline QMG									0.7087
QMG <= 15	13 / 39 (33.3)	4 / 38 (10.5)	- No data to report -						
QMG >= 16	19 / 52 (36.5)	10 / 55 (18.2)							
Baseline MGFA class									0.8449
II	10 / 36 (27.8)	4 / 43 (9.3)	- No data to report -						
III	18 / 49 (36.7)	10 / 49 (20.4)							
IV	5 / 7 (71.4)	1 / 3 (33.3)							
Region									0.3482
Asia	11 / 39 (28.2)	6 / 30 (20.0)	- No data to report -						
Europe	17 / 39 (43.6)	4 / 37 (10.8)							
North America	4 / 12 (33.3)	4 / 19 (21.1)							
Rest of the world	1 / 3 (33.3)	1 / 9 (11.1)							
Region									0.1510
EU	17 / 39 (43.6)	4 / 37 (10.8)	- No data to report -						
Non-EU	16 / 54 (29.6)	11 / 58 (19.0)							
Region									NA
Japan	1 / 1 (100.0)	0 / 1 (0.0)	- No data to report -						
Non-Japan	32 / 92 (34.8)	15 / 94 (16.0)							

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	4 / 22 (18.2)	2 / 21 (9.5)	- No data to report -						
>= 65 years	2 / 2 (100.0)	1 / 3 (33.3)							
Sex									NA
Male	4 / 7 (57.1)	0 / 5 (0.0)	- No data to report -						
Female	2 / 17 (11.8)	3 / 19 (15.8)							
Baseline steroid use									NA
Prednisone <= 20 mg/day	1 / 13 (7.7)	1 / 19 (5.3)	- No data to report -						
Prednisone > 20 mg/day	5 / 10 (50.0)	1 / 2 (50.0)							
Baseline QMG									NA
QMG <= 15	2 / 9 (22.2)	2 / 13 (15.4)	- No data to report -						
QMG >= 16	4 / 15 (26.7)	0 / 9 (0.0)							
Baseline MGFA class									NA
II	4 / 12 (33.3)	1 / 13 (7.7)	- No data to report -						
III	2 / 12 (16.7)	2 / 9 (22.2)							
IV	0 / 0 (-)	0 / 1 (0.0)							
Region									NA
Asia	3 / 15 (20.0)	1 / 14 (7.1)	- No data to report -						
Europe	1 / 2 (50.0)	2 / 7 (28.6)							
North America	0 / 2 (0.0)	0 / 2 (0.0)							
Rest of the world	2 / 5 (40.0)	0 / 1 (0.0)							
Region									NA
EU	1 / 2 (50.0)	2 / 7 (28.6)	- No data to report -						
Non-EU	5 / 22 (22.7)	1 / 17 (5.9)							
Region									NA
Japan	1 / 2 (50.0)	0 / 2 (0.0)	- No data to report -						

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
Non-Japan	5 / 22 (22.7)	3 / 22 (13.6)							

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level. The denominator of the percentage is the N1 under each subgroup. IVIg = Intravenous immunoglobulin. PLEX = Plasma exchange. ER = Emergency room.
[a] Interaction p-value was based on Zelen's exact test for equal odds ratios. If Zero cell correction applied, interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.9 Patient Global Impression of Change (PGIC)

1.9.1 Anteil an Patientinnen und Patienten mit Verbesserung im PGIC (Composite Strategie; Kategorien: sehr stark verbessert oder stark verbessert)

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									0.2743
>= 18 - < 65 years	17 / 59 (28.8)	38 / 59 (64.4)	4.23 (1.93, 9.26)	0.0003	2.24 (1.47, 3.54)	0.0002	34.40 (17.18, 51.63)	<0.0001	
>= 65 years	3 / 7 (42.9)	7 / 15 (46.7)	1.57 (0.19, 13.06)	0.6767	1.09 (0.44, 3.26)	1.0000	9.52 (-32.79, 51.82)	0.6593	
Sex									0.2710
Male	13 / 34 (38.2)	14 / 24 (58.3)	1.93 (0.64, 5.82)	0.2421	1.53 (0.88, 2.65)	0.1828	16.20 (-10.57, 42.96)	0.2356	
Female	7 / 32 (21.9)	31 / 50 (62.0)	5.52 (1.96, 15.55)	0.0012	2.83 (1.52, 5.79)	0.0006	39.66 (18.92, 60.41)	0.0002	
Baseline steroid use									0.1087
Prednisone <= 20 mg/day	16 / 42 (38.1)	29 / 50 (58.0)	2.11 (0.91, 4.91)	0.0837	1.52 (0.99, 2.44)	0.0636	18.43 (-1.95, 38.80)	0.0763	
Prednisone > 20 mg/day	3 / 21 (14.3)	14 / 21 (66.7)	8.79 (1.92, 40.16)	0.0050	4.67 (1.78, 13.82)	0.0013	49.04 (21.38, 76.70)	0.0005	
Baseline QMG									1.0000
QMG <= 15	7 / 26 (26.9)	15 / 26 (57.7)	3.57 (1.10, 11.60)	0.0344	2.14 (1.10, 4.47)	0.0483	30.54 (4.01, 57.08)	0.0241	
QMG >= 16	13 / 38 (34.2)	29 / 46 (63.0)	3.14 (1.25, 7.88)	0.0146	1.84 (1.16, 3.09)	0.0154	27.86 (6.62, 49.09)	0.0101	
Baseline MGFA class									NA
II	8 / 27 (29.6)	16 / 32 (50.0)	NA	NA	NA	NA	NA	NA	
III	12 / 33 (36.4)	28 / 39 (71.8)	NA	NA	NA	NA	NA	NA	
IV	0 / 5 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	13 / 26 (50.0)	14 / 22 (63.6)	NA	NA	NA	NA	NA	NA	
Europe	2 / 29 (6.9)	18 / 31 (58.1)	NA	NA	NA	NA	NA	NA	
North America	5 / 9 (55.6)	8 / 14 (57.1)	NA	NA	NA	NA	NA	NA	

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
Rest of the world	0 / 2 (0.0)	5 / 7 (71.4)	NA	NA	NA	NA	NA	NA	
Region									0.0109
EU	2 / 29 (6.9)	18 / 31 (58.1)	16.55 (3.34, 81.98)	0.0006	8.42 (2.52, 31.14)	<0.0001	52.70 (26.39, 79.01)	<0.0001	
Non-EU	18 / 37 (48.6)	27 / 43 (62.8)	1.65 (0.67, 4.09)	0.2759	1.29 (0.87, 1.98)	0.2600	12.41 (-9.75, 34.58)	0.2724	
Region									NA
Japan	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	20 / 66 (30.3)	44 / 73 (60.3)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	10 / 19 (52.6)	14 / 21 (66.7)	NA	NA	NA	NA	NA	NA	
>= 65 years	0 / 2 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	
Sex									1.0000
Male	3 / 7 (42.9)	3 / 5 (60.0)	ND	ND	1.40 (0.44, 4.34)	1.0000	ND	ND	
Female	7 / 14 (50.0)	12 / 19 (63.2)	1.83 (0.42, 7.97)	0.4233	1.26 (0.70, 2.51)	0.4969	14.85 (-21.13, 50.83)	0.4185	
Baseline steroid use									1.0000
Prednisone <= 20 mg/day	5 / 11 (45.5)	13 / 19 (68.4)	2.39 (0.51, 11.22)	0.2701	1.51 (0.80, 3.36)	0.2663	21.20 (-15.67, 58.08)	0.2598	
Prednisone > 20 mg/day	4 / 9 (44.4)	1 / 2 (50.0)	1.17 (0.04, 33.09)	0.9257	1.13 (0.19, 3.69)	1.0000	3.96 (-79.46, 87.38)	0.9258	
Baseline QMG									0.5363
QMG <= 15	4 / 8 (50.0)	7 / 13 (53.8)	1.22 (0.18, 8.22)	0.8357	1.08 (0.48, 2.76)	1.0000	5.03 (-42.32, 52.37)	0.8352	
QMG >= 16	6 / 13 (46.2)	7 / 9 (77.8)	3.35 (0.49, 22.75)	0.2165	1.69 (0.83, 3.53)	0.2031	27.76 (-13.02, 68.54)	0.1821	

			Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
	Placebo	Inebilizumab	Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
Baseline MGFA class									NA
II	5 / 10 (50.0)	8 / 13 (61.5)	NA	NA	NA	NA	NA	NA	
III	5 / 11 (45.5)	6 / 9 (66.7)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	5 / 13 (38.5)	10 / 14 (71.4)	NA	NA	NA	NA	NA	NA	
Europe	2 / 2 (100.0)	3 / 7 (42.9)	NA	NA	NA	NA	NA	NA	
North America	1 / 2 (50.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	2 / 4 (50.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	2 / 2 (100.0)	3 / 7 (42.9)	NA	NA	NA	NA	NA	NA	
Non-EU	8 / 19 (42.1)	12 / 17 (70.6)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	0 / 1 (0.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	10 / 20 (50.0)	13 / 22 (59.1)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
PGIC = Patient Global Impression of Change. MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. N = Number of subjects in analysis set. n = Number of responders. N1 = Number of subjects with assessment in each subgroup level. CI = Confidence interval. RCP = Randomized controlled period.
Composite strategy: The analyses include all data collected by Week 26. If a subject used rescue therapy after Day 28 during RCP, the data collected on or after the initiation of the rescue therapy were imputed using the subject's worst observation collected.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), and baseline MG-ADL score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.10 Neuro-QoL Fatigue

1.10.1 Anteil an Patientinnen und Patienten mit Verbesserung des Neuro-QoL Fatigue um ≥ 12 Punkte (keine Rescue-Therapie)

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	16 / 68 (23.5)	25 / 62 (40.3)	2.65 (1.21, 5.84)	0.0154	1.71 (1.03, 2.91)	0.0582	20.93 (4.19, 37.68)	0.0143	
>= 65 years	2 / 10 (20.0)	6 / 17 (35.3)	1.11 (0.11, 11.24)	0.9326	1.76 (0.52, 6.94)	0.6655	2.30 (-50.62, 55.23)	0.9320	
Sex									0.4693
Male	11 / 39 (28.2)	10 / 27 (37.0)	1.51 (0.48, 4.77)	0.4869	1.31 (0.65, 2.61)	0.5918	8.51 (-16.00, 33.01)	0.4963	
Female	7 / 39 (17.9)	21 / 52 (40.4)	3.15 (1.14, 8.67)	0.0264	2.25 (1.12, 4.79)	0.0241	23.92 (4.55, 43.28)	0.0155	
Baseline steroid use									1.0000
Prednisone <= 20 mg/day	12 / 47 (25.5)	21 / 52 (40.4)	2.15 (0.88, 5.27)	0.0935	1.58 (0.89, 2.88)	0.1385	17.14 (-2.46, 36.75)	0.0866	
Prednisone > 20 mg/day	6 / 26 (23.1)	8 / 24 (33.3)	ND	ND	1.44 (0.60, 3.52)	0.5330	ND	ND	
Baseline QMG									1.0000
QMG <= 15	7 / 31 (22.6)	10 / 29 (34.5)	1.88 (0.55, 6.51)	0.3168	1.53 (0.69, 3.46)	0.3937	13.82 (-13.19, 40.83)	0.3161	
QMG >= 16	11 / 45 (24.4)	20 / 48 (41.7)	2.48 (0.99, 6.21)	0.0531	1.70 (0.94, 3.17)	0.1227	19.85 (0.45, 39.25)	0.0449	
Baseline MGFA class									0.4995
II	6 / 29 (20.7)	15 / 35 (42.9)	2.50 (0.72, 8.67)	0.1496	2.07 (0.97, 4.70)	0.0687	19.09 (-6.03, 44.22)	0.1364	
III	11 / 41 (26.8)	15 / 41 (36.6)	1.59 (0.60, 4.16)	0.3498	1.36 (0.72, 2.61)	0.4769	9.83 (-10.84, 30.50)	0.3511	
IV	0 / 7 (0.0)	1 / 3 (33.3)	ND	ND	6.00 (0.57, 65.88)	0.3000	ND	ND	
Region									0.2824
Asia	10 / 31 (32.3)	11 / 26 (42.3)	1.25 (0.40, 3.93)	0.6973	1.31 (0.67, 2.58)	0.5823	4.07 (-16.73, 24.86)	0.7014	
Europe	3 / 33 (9.1)	12 / 32 (37.5)	7.37 (1.70, 31.95)	0.0076	4.13 (1.41, 12.81)	0.0084	35.74 (9.27, 62.22)	0.0081	

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
North America	5 / 11 (45.5)	6 / 14 (42.9)	1.28 (0.23, 7.24)	0.7816	0.94 (0.39, 2.35)	1.0000	6.12 (-37.03, 49.26)	0.7811	
Rest of the world	0 / 3 (0.0)	2 / 7 (28.6)	ND	ND	2.50 (0.32, 26.21)	1.0000	ND	ND	
Region									0.1302
EU	3 / 33 (9.1)	12 / 32 (37.5)	7.37 (1.70, 31.95)	0.0076	4.13 (1.41, 12.81)	0.0084	35.74 (9.27, 62.22)	0.0081	
Non-EU	15 / 45 (33.3)	19 / 47 (40.4)	1.36 (0.57, 3.27)	0.4915	1.21 (0.71, 2.09)	0.5226	7.17 (-13.13, 27.47)	0.4887	
Region									NA
Japan	0 / 1 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	18 / 77 (23.4)	31 / 78 (39.7)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	8 / 20 (40.0)	12 / 21 (57.1)	NA	NA	NA	NA	NA	NA	
>= 65 years	0 / 2 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	
Sex									0.0608
Male	4 / 7 (57.1)	1 / 5 (20.0)	ND	ND	0.35 (0.06, 1.56)	0.2929	ND	ND	
Female	4 / 15 (26.7)	12 / 19 (63.2)	2.79 (0.59, 13.19)	0.1942	2.37 (1.06, 6.08)	0.0454	25.10 (-11.01, 61.21)	0.1731	
Baseline steroid use									0.2032
Prednisone <= 20 mg/day	4 / 12 (33.3)	12 / 19 (63.2)	3.22 (0.60, 17.21)	0.1722	1.89 (0.89, 4.80)	0.1489	27.16 (-10.82, 65.14)	0.1611	
Prednisone > 20 mg/day	3 / 9 (33.3)	0 / 2 (0.0)	ND	ND	0.48 (0.05, 3.08)	1.0000	ND	ND	
Baseline QMG									0.2537
QMG <= 15	3 / 8 (37.5)	5 / 13 (38.5)	1.21 (0.17, 8.78)	0.8497	1.03 (0.36, 3.27)	1.0000	4.65 (-43.13, 52.43)	0.8488	
QMG >= 16	5 / 14 (35.7)	7 / 9 (77.8)	6.34 (0.64, 63.12)	0.1150	2.18 (1.00, 5.00)	0.0894	38.40 (-3.94, 80.74)	0.0755	
Baseline MGFA class									NA

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
II	4 / 11 (36.4)	7 / 13 (53.8)	NA	NA	NA	NA	NA	NA	
III	4 / 11 (36.4)	5 / 9 (55.6)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	4 / 14 (28.6)	7 / 14 (50.0)	NA	NA	NA	NA	NA	NA	
Europe	1 / 2 (50.0)	4 / 7 (57.1)	NA	NA	NA	NA	NA	NA	
North America	2 / 2 (100.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	1 / 4 (25.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	1 / 2 (50.0)	4 / 7 (57.1)	NA	NA	NA	NA	NA	NA	
Non-EU	7 / 20 (35.0)	9 / 17 (52.9)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	0 / 1 (0.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	8 / 21 (38.1)	11 / 22 (50.0)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
Neuro-QoL = Quality of Life in Neurological Disorders. MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects with assessment in each subgroup level. CI = Confidence interval.
Baseline is defined as the last valid value on or prior to the 1st dose of Randomized controlled period.
If a subject used rescue therapy between Day 28 and Week 26 or discontinued from the study before Week 26, the subject was considered as a non-responder.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), baseline MGADL score, and baseline Neuro-QoL Fatigue score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.11 Myasthenia gravis Quality of Life-15, revised (MG-QoL-15r)

1.11.1 Anteil an Patientinnen und Patienten mit Verbesserung des MG-QoL-15r um ≥ 5 Punkte (keine Rescue-Therapie)

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio[a] Pt Est (95% CI)	Odds Ratio[a] p-value	Risk Ratio Pt Est (95% CI)	Risk Ratio p-value	Risk Difference[a] (%) Pt Est (95% CI)	Risk Difference[a] (%) p-value	Treatment by Subgroup Interaction p-value
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	20 / 68 (29.4)	30 / 62 (48.4)	2.80 (1.30, 6.02)	0.0086	1.65 (1.06, 2.59)	0.0312	24.94 (7.05, 42.82)	0.0063	
>= 65 years	1 / 10 (10.0)	6 / 17 (35.3)	2.35 (0.20, 27.44)	0.4955	3.53 (0.71, 21.18)	0.2040	14.77 (-22.43, 51.97)	0.4365	
Sex									0.0349
Male	14 / 39 (35.9)	9 / 27 (33.3)	1.06 (0.34, 3.24)	0.9226	0.93 (0.46, 1.78)	1.0000	1.27 (-24.48, 27.03)	0.9227	
Female	7 / 39 (17.9)	27 / 52 (51.9)	4.90 (1.79, 13.41)	0.0020	2.89 (1.48, 6.02)	0.0010	35.37 (15.76, 54.99)	0.0004	
Baseline steroid use									0.2648
Prednisone <= 20 mg/day	16 / 47 (34.0)	24 / 52 (46.2)	1.81 (0.77, 4.25)	0.1728	1.36 (0.84, 2.25)	0.3052	14.45 (-6.00, 34.91)	0.1661	
Prednisone > 20 mg/day	4 / 26 (15.4)	11 / 24 (45.8)	4.26 (1.10, 16.49)	0.0359	2.98 (1.18, 8.05)	0.0302	30.25 (3.79, 56.70)	0.0251	
Baseline QMG									0.4821
QMG <= 15	10 / 31 (32.3)	12 / 29 (41.4)	1.61 (0.52, 4.98)	0.4087	1.28 (0.66, 2.51)	0.5933	11.54 (-15.67, 38.74)	0.4059	
QMG >= 16	11 / 45 (24.4)	23 / 48 (47.9)	3.12 (1.24, 7.81)	0.0152	1.96 (1.11, 3.59)	0.0305	25.98 (6.11, 45.85)	0.0104	
Baseline MGFA class									0.2962
II	8 / 29 (27.6)	14 / 35 (40.0)	1.74 (0.54, 5.61)	0.3518	1.45 (0.73, 3.00)	0.4283	12.21 (-12.99, 37.40)	0.3424	
III	13 / 41 (31.7)	20 / 41 (48.8)	2.10 (0.82, 5.40)	0.1219	1.54 (0.90, 2.69)	0.1763	18.30 (-4.39, 41.00)	0.1140	
IV	0 / 7 (0.0)	2 / 3 (66.7)	ND	ND	10.00 (1.14, 100.51)	0.0667	ND	ND	
Region									0.1914
Asia	12 / 31 (38.7)	13 / 26 (50.0)	1.55 (0.51, 4.77)	0.4424	1.29 (0.72, 2.34)	0.4323	10.54 (-16.43, 37.52)	0.4436	
Europe	3 / 33 (9.1)	12 / 32 (37.5)	6.15 (1.51, 25.06)	0.0112	4.13 (1.41, 12.81)	0.0084	34.72 (8.28, 61.17)	0.0101	

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
North America	6 / 11 (54.5)	7 / 14 (50.0)	0.87 (0.16, 4.81)	0.8762	0.92 (0.43, 2.03)	1.0000	-3.37 (-45.74, 39.00)	0.8761	
Rest of the world	0 / 3 (0.0)	4 / 7 (57.1)	ND	ND	4.50 (0.70, 44.25)	0.2000	ND	ND	
Region									0.1417
EU	3 / 33 (9.1)	12 / 32 (37.5)	6.15 (1.51, 25.06)	0.0112	4.13 (1.41, 12.81)	0.0084	34.72 (8.28, 61.17)	0.0101	
Non-EU	18 / 45 (40.0)	24 / 47 (51.1)	1.65 (0.69, 3.96)	0.2621	1.28 (0.82, 2.03)	0.3040	12.43 (-9.06, 33.93)	0.2569	
Region									NA
Japan	0 / 1 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	21 / 77 (27.3)	36 / 78 (46.2)	NA	NA	NA	NA	NA	NA	
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	9 / 20 (45.0)	14 / 21 (66.7)	NA	NA	NA	NA	NA	NA	
>= 65 years	0 / 2 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	
Sex									0.0480
Male	4 / 7 (57.1)	1 / 5 (20.0)	ND	ND	0.35 (0.06, 1.56)	0.2929	ND	ND	
Female	5 / 15 (33.3)	14 / 19 (73.7)	3.87 (0.79, 19.10)	0.0963	2.21 (1.13, 5.02)	0.0359	31.51 (-4.13, 67.15)	0.0831	
Baseline steroid use									1.0000
Prednisone <= 20 mg/day	5 / 12 (41.7)	12 / 19 (63.2)	2.47 (0.50, 12.14)	0.2670	1.52 (0.77, 3.45)	0.2883	20.63 (-15.80, 57.07)	0.2670	
Prednisone > 20 mg/day	3 / 9 (33.3)	1 / 2 (50.0)	2.99 (0.09, 104.74)	0.5456	1.50 (0.25, 5.68)	1.0000	26.37 (-51.70, 104.44)	0.5080	
Baseline QMG									1.0000
QMG <= 15	3 / 8 (37.5)	7 / 13 (53.8)	1.60 (0.24, 10.89)	0.6310	1.44 (0.57, 4.28)	0.6594	11.69 (-35.54, 58.92)	0.6275	
QMG >= 16	6 / 14 (42.9)	7 / 9 (77.8)	7.11 (0.51, 99.67)	0.1456	1.81 (0.88, 3.83)	0.1968	34.77 (-15.21, 84.75)	0.1727	
Baseline MGFA class									NA

Subgroup	Placebo	Inebilizumab	Inebilizumab vs. Placebo						Treatment by Subgroup Interaction p-value
			Odds Ratio[a]		Risk Ratio		Risk Difference[a] (%)		
	n / N1 (%)	n / N1 (%)	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	Pt Est (95% CI)	p-value	
II	3 / 11 (27.3)	7 / 13 (53.8)	NA	NA	NA	NA	NA	NA	
III	6 / 11 (54.5)	7 / 9 (77.8)	NA	NA	NA	NA	NA	NA	
IV	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
Asia	5 / 14 (35.7)	8 / 14 (57.1)	NA	NA	NA	NA	NA	NA	
Europe	1 / 2 (50.0)	5 / 7 (71.4)	NA	NA	NA	NA	NA	NA	
North America	1 / 2 (50.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	
Rest of the world	2 / 4 (50.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	
Region									NA
EU	1 / 2 (50.0)	5 / 7 (71.4)	NA	NA	NA	NA	NA	NA	
Non-EU	8 / 20 (40.0)	10 / 17 (58.8)	NA	NA	NA	NA	NA	NA	
Region									NA
Japan	0 / 1 (0.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	
Non-Japan	9 / 21 (42.9)	13 / 22 (59.1)	NA	NA	NA	NA	NA	NA	

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
MG-QoL15r = Myasthenia Gravis Quality of Life-15, revised. MG-ADL = Myasthenia Gravis Activities of Daily Living. QMG = Quantitative Myasthenia Gravis. n = Number of responders. N1 = Number of subjects with assessment in each subgroup level. CI = Confidence interval.
Baseline is defined as the last valid value on or prior to the 1st dose of Randomized controlled period.
If a subject used rescue therapy between Day 28 and Week 26 or discontinued from the study before Week 26, the subject was considered as a non-responder.
[a] Based on logistic regression with treatment, baseline steroid use (Daily dose <= 5 mg vs > 5 mg), baseline QMG score (QMG <= 15 vs QMG >= 16), baseline MGADL score, and baseline MG-QoL score as common covariates.
95% CI for risk ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.12 Sicherheitsrelevante Endpunkte

1.12.1 Gesamtraten: UE

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						
			Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
AChR+ Population (Week 52)									
Age									0.3772
>= 18 - < 65 years	62 / 81 (76.5)	61 / 76 (80.3)	1.25	(0.59, 2.65)	1.05	(0.88, 1.24)	3.72	(-9.35, 16.60)	0.6987
>= 65 years	8 / 14 (57.1)	16 / 19 (84.2)	4.00	(0.84, 18.73)	1.47	(0.95, 2.64)	27.07	(-3.68, 55.35)	0.1220
Sex									0.4807
Male	36 / 46 (78.3)	28 / 35 (80.0)	1.11	(0.38, 3.19)	1.02	(0.79, 1.29)	1.74	(-17.06, 19.23)	1.0000
Female	34 / 49 (69.4)	49 / 60 (81.7)	1.97	(0.82, 4.73)	1.18	(0.95, 1.50)	12.28	(-3.80, 28.62)	0.1760
Baseline steroid use									1.0000
Prednisone <= 20 mg/day	35 / 55 (63.6)	48 / 63 (76.2)	1.83	(0.83, 4.03)	1.20	(0.94, 1.55)	12.55	(-3.96, 28.83)	0.1601
Prednisone > 20 mg/day	26 / 31 (83.9)	24 / 27 (88.9)	1.54	(0.36, 6.47)	1.06	(0.84, 1.35)	5.02	(-14.45, 23.65)	0.7119
Baseline QMG									0.4767
QMG <= 15	27 / 39 (69.2)	27 / 38 (71.1)	1.09	(0.42, 2.85)	1.03	(0.76, 1.39)	1.82	(-18.56, 22.00)	1.0000
QMG >= 16	40 / 53 (75.5)	48 / 55 (87.3)	2.23	(0.83, 5.96)	1.16	(0.96, 1.42)	11.80	(-2.96, 26.74)	0.1406
Baseline MGFA class									1.0000
II	25 / 36 (69.4)	34 / 43 (79.1)	1.66	(0.61, 4.53)	1.14	(0.88, 1.53)	9.63	(-9.59, 29.05)	0.4369
III	39 / 49 (79.6)	41 / 49 (83.7)	1.31	(0.48, 3.58)	1.05	(0.86, 1.29)	4.08	(-11.62, 19.79)	0.7948
IV	5 / 8 (62.5)	2 / 3 (66.7)	1.20	(0.10, 12.94)	1.07	(0.31, 2.55)	4.17	(-52.62, 51.71)	1.0000
Region									0.1429
Asia	29 / 40 (72.5)	27 / 30 (90.0)	3.41	(0.91, 12.55)	1.24	(0.98, 1.60)	17.50	(-1.61, 34.91)	0.0805
Europe	28 / 40 (70.0)	23 / 37 (62.2)	0.70	(0.28, 1.80)	0.89	(0.63, 1.23)	-7.84	(-28.44, 13.17)	0.4819
North America	11 / 12 (91.7)	18 / 19 (94.7)	1.64	(0.16, 17.31)	1.03	(0.81, 1.48)	3.07	(-18.01, 31.00)	1.0000
Rest of the world	2 / 3 (66.7)	9 / 9 (100.0)	11.40	(0.65, 172.05)	1.52	(0.90, 4.36)	32.50	(-8.12, 74.71)	0.2500
Region									0.0314
EU	28 / 40 (70.0)	23 / 37 (62.2)	0.70	(0.28, 1.80)	0.89	(0.63, 1.23)	-7.84	(-28.44, 13.17)	0.4819

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
Non-EU	42 / 55 (76.4)	54 / 58 (93.1)	4.18	(1.33, 13.04)	1.22	(1.05, 1.48)	16.74	(3.79, 30.49)	0.0172
Region									NA
Japan	0 / 1 (0.0)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	70 / 94 (74.5)	76 / 94 (80.9)	NA	NA	NA	NA	NA	NA	NA
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	16 / 22 (72.7)	17 / 21 (81.0)	NA	NA	NA	NA	NA	NA	NA
>= 65 years	1 / 2 (50.0)	2 / 3 (66.7)	NA	NA	NA	NA	NA	NA	NA
Sex									0.1345
Male	7 / 7 (100.0)	4 / 5 (80.0)	0.20	(0.01, 3.22)	0.80	(0.38, 1.35)	-18.75	(-59.26, 21.75)	0.4167
Female	10 / 17 (58.8)	15 / 19 (78.9)	2.63	(0.63, 10.77)	1.34	(0.86, 2.27)	20.12	(-10.04, 47.80)	0.2814
Baseline steroid use									0.5563
Prednisone <= 20 mg/day	7 / 13 (53.8)	14 / 19 (73.7)	2.40	(0.56, 10.28)	1.37	(0.81, 2.63)	19.84	(-13.12, 50.41)	0.2826
Prednisone > 20 mg/day	9 / 10 (90.0)	2 / 2 (100.0)	0.79	(0.04, 11.64)	0.96	(0.35, 1.56)	-3.03	(-58.65, 32.58)	1.0000
Baseline QMG									1.0000
QMG <= 15	6 / 9 (66.7)	10 / 13 (76.9)	1.67	(0.28, 10.01)	1.15	(0.67, 2.27)	10.26	(-26.12, 47.20)	0.6550
QMG >= 16	11 / 15 (73.3)	7 / 9 (77.8)	1.27	(0.20, 7.55)	1.06	(0.59, 1.73)	4.44	(-33.37, 36.46)	1.0000
Baseline MGFA class									NA
II	7 / 12 (58.3)	9 / 13 (69.2)	NA	NA	NA	NA	NA	NA	NA
III	10 / 12 (83.3)	8 / 9 (88.9)	NA	NA	NA	NA	NA	NA	NA
IV	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	10 / 15 (66.7)	10 / 14 (71.4)	NA	NA	NA	NA	NA	NA	NA
Europe	2 / 2 (100.0)	7 / 7 (100.0)	NA	NA	NA	NA	NA	NA	NA

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						
			Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
North America	2 / 2 (100.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	NA
Rest of the world	3 / 5 (60.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
EU	2 / 2 (100.0)	7 / 7 (100.0)	NA	NA	NA	NA	NA	NA	NA
Non-EU	15 / 22 (68.2)	12 / 17 (70.6)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Japan	1 / 2 (50.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	16 / 22 (72.7)	18 / 22 (81.8)	NA	NA	NA	NA	NA	NA	NA

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level.
Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal
Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).
95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.12.2 Gesamtraten: SUE

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio Pt Est	Odds Ratio (95% CI)	Risk Ratio Pt Est	Risk Ratio (95% CI)	Risk Difference (%) Pt Est	Risk Difference (%) (95% CI)	p-value
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	12 / 81 (14.8)	6 / 76 (7.9)	0.49	(0.18, 1.35)	0.53	(0.22, 1.30)	-6.92	(-17.38, 3.30)	0.2142
>= 65 years	3 / 14 (21.4)	2 / 19 (10.5)	0.43	(0.07, 2.58)	0.49	(0.11, 2.21)	-10.90	(-39.18, 14.65)	0.6285
Sex									0.6236
Male	10 / 46 (21.7)	6 / 35 (17.1)	0.74	(0.25, 2.23)	0.79	(0.32, 1.88)	-4.60	(-21.62, 13.82)	0.7795
Female	5 / 49 (10.2)	2 / 60 (3.3)	0.30	(0.07, 1.43)	0.33	(0.08, 1.40)	-6.87	(-18.87, 2.75)	0.2396
Baseline steroid use									0.6525
Prednisone <= 20 mg/day	8 / 55 (14.5)	6 / 63 (9.5)	0.62	(0.21, 1.84)	0.65	(0.25, 1.70)	-5.02	(-17.95, 6.99)	0.5696
Prednisone > 20 mg/day	6 / 31 (19.4)	2 / 27 (7.4)	0.33	(0.07, 1.62)	0.38	(0.09, 1.50)	-11.95	(-30.34, 6.85)	0.2633
Baseline QMG									0.6470
QMG <= 15	6 / 39 (15.4)	2 / 38 (5.3)	0.31	(0.07, 1.44)	0.34	(0.08, 1.38)	-10.12	(-25.37, 4.13)	0.2626
QMG >= 16	9 / 53 (17.0)	6 / 55 (10.9)	0.60	(0.20, 1.76)	0.64	(0.25, 1.62)	-6.07	(-19.94, 7.37)	0.4136
Baseline MGFA class									NA
II	7 / 36 (19.4)	3 / 43 (7.0)	0.31	(0.08, 1.21)	0.36	(0.11, 1.18)	-12.47	(-29.14, 2.43)	0.1723
III	8 / 49 (16.3)	5 / 49 (10.2)	0.58	(0.18, 1.84)	0.63	(0.23, 1.69)	-6.12	(-20.42, 7.86)	0.5529
IV	0 / 8 (0.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									0.6314
Asia	9 / 40 (22.5)	5 / 30 (16.7)	0.69	(0.21, 2.24)	0.74	(0.28, 1.88)	-5.83	(-24.11, 14.14)	0.7637
Europe	2 / 40 (5.0)	0 / 37 (0.0)	0.21	(0.02, 2.41)	0.22	(0.02, 2.31)	-4.78	(-16.69, 5.92)	0.4942
North America	3 / 12 (25.0)	3 / 19 (15.8)	0.56	(0.10, 3.01)	0.63	(0.17, 2.45)	-9.21	(-40.55, 18.81)	0.6526
Rest of the world	1 / 3 (33.3)	0 / 9 (0.0)	0.09	(0.01, 1.54)	0.13	(0.01, 1.43)	-32.50	(-74.71, 8.12)	0.2500
Region									0.5639
EU	2 / 40 (5.0)	0 / 37 (0.0)	0.21	(0.02, 2.41)	0.22	(0.02, 2.31)	-4.78	(-16.69, 5.92)	0.4942
Non-EU	13 / 55 (23.6)	8 / 58 (13.8)	0.52	(0.20, 1.34)	0.58	(0.27, 1.27)	-9.84	(-24.54, 4.64)	0.2285
Region									NA

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
Japan	0 / 1 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	15 / 94 (16.0)	8 / 94 (8.5)	NA	NA	NA	NA	NA	NA	NA
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	1 / 22 (4.5)	1 / 21 (4.8)	NA	NA	NA	NA	NA	NA	NA
>= 65 years	0 / 2 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	NA
Sex									NA
Male	1 / 7 (14.3)	0 / 5 (0.0)	NA	NA	NA	NA	NA	NA	NA
Female	0 / 17 (0.0)	2 / 19 (10.5)	NA	NA	NA	NA	NA	NA	NA
Baseline steroid use									NA
Prednisone <= 20 mg/day	0 / 13 (0.0)	0 / 19 (0.0)	NA	NA	NA	NA	NA	NA	NA
Prednisone > 20 mg/day	1 / 10 (10.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	NA
Baseline QMG									NA
QMG <= 15	0 / 9 (0.0)	2 / 13 (15.4)	NA	NA	NA	NA	NA	NA	NA
QMG >= 16	1 / 15 (6.7)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline MGFA class									NA
II	0 / 12 (0.0)	1 / 13 (7.7)	NA	NA	NA	NA	NA	NA	NA
III	1 / 12 (8.3)	1 / 9 (11.1)	NA	NA	NA	NA	NA	NA	NA
IV	0 / 0 (-)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	1 / 15 (6.7)	1 / 14 (7.1)	NA	NA	NA	NA	NA	NA	NA
Europe	0 / 2 (0.0)	1 / 7 (14.3)	NA	NA	NA	NA	NA	NA	NA
North America	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Rest of the world	0 / 5 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
EU	0 / 2 (0.0)	1 / 7 (14.3)	NA	NA	NA	NA	NA	NA	NA
Non-EU	1 / 22 (4.5)	1 / 17 (5.9)	NA	NA	NA	NA	NA	NA	NA
Region									NA

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
Japan	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	1 / 22 (4.5)	2 / 22 (9.1)	NA	NA	NA	NA	NA	NA	NA

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level.
Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal
Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).
95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.12.3 Gesamtraten: Schwere UE (CTCAE Grad ≥ 3)

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						
			Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
AChR+ Population (Week 52)									
Age									1.0000
>= 18 - < 65 years	9 / 81 (11.1)	7 / 76 (9.2)	0.81	(0.30, 2.23)	0.83	(0.33, 2.05)	-1.90	(-11.90, 8.18)	0.7947
>= 65 years	2 / 14 (14.3)	3 / 19 (15.8)	1.13	(0.19, 6.54)	1.11	(0.25, 5.11)	1.50	(-27.00, 26.66)	1.0000
Sex									1.0000
Male	7 / 46 (15.2)	6 / 35 (17.1)	1.15	(0.37, 3.65)	1.13	(0.43, 2.93)	1.93	(-14.22, 19.57)	1.0000
Female	4 / 49 (8.2)	4 / 60 (6.7)	0.80	(0.21, 3.11)	0.82	(0.23, 2.86)	-1.50	(-13.40, 9.10)	1.0000
Baseline steroid use									0.6501
Prednisone <= 20 mg/day	4 / 55 (7.3)	6 / 63 (9.5)	1.34	(0.38, 4.69)	1.31	(0.42, 4.16)	2.25	(-9.01, 13.15)	0.7491
Prednisone > 20 mg/day	6 / 31 (19.4)	4 / 27 (14.8)	0.72	(0.19, 2.74)	0.77	(0.25, 2.27)	-4.54	(-24.31, 16.20)	0.7371
Baseline QMG									1.0000
QMG <= 15	3 / 39 (7.7)	3 / 38 (7.9)	1.03	(0.22, 4.79)	1.03	(0.25, 4.23)	0.20	(-13.66, 14.28)	1.0000
QMG >= 16	8 / 53 (15.1)	7 / 55 (12.7)	0.82	(0.28, 2.37)	0.84	(0.34, 2.09)	-2.37	(-16.19, 11.19)	0.7857
Baseline MGFA class									0.5026
II	6 / 36 (16.7)	4 / 43 (9.3)	0.51	(0.14, 1.86)	0.56	(0.18, 1.71)	-7.36	(-24.00, 7.79)	0.4988
III	4 / 49 (8.2)	6 / 49 (12.2)	1.57	(0.44, 5.55)	1.50	(0.48, 4.72)	4.08	(-8.77, 17.34)	0.7404
IV	1 / 8 (12.5)	0 / 3 (0.0)	0.71	(0.05, 12.36)	0.75	(0.07, 7.17)	-4.17	(-41.43, 47.95)	1.0000
Region									0.2712
Asia	6 / 40 (15.0)	6 / 30 (20.0)	1.42	(0.43, 4.72)	1.33	(0.49, 3.58)	5.00	(-12.85, 24.51)	0.7503
Europe	2 / 40 (5.0)	0 / 37 (0.0)	0.21	(0.02, 2.41)	0.22	(0.02, 2.31)	-4.78	(-16.69, 5.92)	0.4942
North America	2 / 12 (16.7)	4 / 19 (21.1)	1.33	(0.23, 7.40)	1.26	(0.32, 5.43)	4.39	(-27.42, 31.12)	1.0000
Rest of the world	1 / 3 (33.3)	0 / 9 (0.0)	0.09	(0.01, 1.54)	0.13	(0.01, 1.43)	-32.50	(-74.71, 8.12)	0.2500
Region									0.2820
EU	2 / 40 (5.0)	0 / 37 (0.0)	0.21	(0.02, 2.41)	0.22	(0.02, 2.31)	-4.78	(-16.69, 5.92)	0.4942

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						
			Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
Non-EU	9 / 55 (16.4)	10 / 58 (17.2)	1.06	(0.41, 2.79)	1.05	(0.47, 2.36)	0.88	(-13.42, 14.98)	1.0000
Region									NA
Japan	0 / 1 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	11 / 94 (11.7)	10 / 94 (10.6)	NA	NA	NA	NA	NA	NA	NA
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	2 / 22 (9.1)	1 / 21 (4.8)	NA	NA	NA	NA	NA	NA	NA
>= 65 years	0 / 2 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	NA
Sex									NA
Male	1 / 7 (14.3)	0 / 5 (0.0)	NA	NA	NA	NA	NA	NA	NA
Female	1 / 17 (5.9)	2 / 19 (10.5)	NA	NA	NA	NA	NA	NA	NA
Baseline steroid use									NA
Prednisone <= 20 mg/day	1 / 13 (7.7)	1 / 19 (5.3)	NA	NA	NA	NA	NA	NA	NA
Prednisone > 20 mg/day	1 / 10 (10.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	NA
Baseline QMG									NA
QMG <= 15	0 / 9 (0.0)	2 / 13 (15.4)	NA	NA	NA	NA	NA	NA	NA
QMG >= 16	2 / 15 (13.3)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline MGFA class									NA
II	0 / 12 (0.0)	2 / 13 (15.4)	NA	NA	NA	NA	NA	NA	NA
III	2 / 12 (16.7)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	NA
IV	0 / 0 (-)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	1 / 15 (6.7)	1 / 14 (7.1)	NA	NA	NA	NA	NA	NA	NA
Europe	0 / 2 (0.0)	1 / 7 (14.3)	NA	NA	NA	NA	NA	NA	NA
North America	1 / 2 (50.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Rest of the world	0 / 5 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA

	Placebo	Inebilizumab	Inebilizumab vs. Placebo						
			Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
EU	0 / 2 (0.0)	1 / 7 (14.3)	NA	NA	NA	NA	NA	NA	NA
Non-EU	2 / 22 (9.1)	1 / 17 (5.9)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Japan	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	2 / 22 (9.1)	2 / 22 (9.1)	NA	NA	NA	NA	NA	NA	NA

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level.
Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal
Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).
95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.
If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

1.12.4 Gesamtraten: Therapieabbruch aufgrund von UE

Subgroup	Placebo n / N1 (%)	Inebilizumab n / N1 (%)	Inebilizumab vs. Placebo: Odds Ratio Pt Est	Odds Ratio (95% CI)	Risk Ratio Pt Est	Risk Ratio (95% CI)	Risk Difference (%) Pt Est	Risk Difference (%) (95% CI)	p-value
AChR+ Population (Week 52)									
Age									NA
>= 18 - < 65 years	1 / 81 (1.2)	1 / 76 (1.3)	NA	NA	NA	NA	NA	NA	NA
>= 65 years	0 / 14 (0.0)	1 / 19 (5.3)	NA	NA	NA	NA	NA	NA	NA
Sex									NA
Male	1 / 46 (2.2)	1 / 35 (2.9)	NA	NA	NA	NA	NA	NA	NA
Female	0 / 49 (0.0)	1 / 60 (1.7)	NA	NA	NA	NA	NA	NA	NA
Baseline steroid use									NA
Prednisone <= 20 mg/day	0 / 55 (0.0)	1 / 63 (1.6)	NA	NA	NA	NA	NA	NA	NA
Prednisone > 20 mg/day	1 / 31 (3.2)	1 / 27 (3.7)	NA	NA	NA	NA	NA	NA	NA
Baseline QMG									NA
QMG <= 15	1 / 39 (2.6)	2 / 38 (5.3)	NA	NA	NA	NA	NA	NA	NA
QMG >= 16	0 / 53 (0.0)	0 / 55 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline MGFA class									NA
II	1 / 36 (2.8)	2 / 43 (4.7)	NA	NA	NA	NA	NA	NA	NA
III	0 / 49 (0.0)	0 / 49 (0.0)	NA	NA	NA	NA	NA	NA	NA
IV	0 / 8 (0.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	0 / 40 (0.0)	2 / 30 (6.7)	NA	NA	NA	NA	NA	NA	NA
Europe	0 / 40 (0.0)	0 / 37 (0.0)	NA	NA	NA	NA	NA	NA	NA
North America	0 / 12 (0.0)	0 / 19 (0.0)	NA	NA	NA	NA	NA	NA	NA
Rest of the world	1 / 3 (33.3)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
EU	0 / 40 (0.0)	0 / 37 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-EU	1 / 55 (1.8)	2 / 58 (3.4)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Japan	0 / 1 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	1 / 94 (1.1)	2 / 94 (2.1)	NA	NA	NA	NA	NA	NA	NA

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
MuSK+ Population (Week 26)									
Age									NA
>= 18 - < 65 years	0 / 22 (0.0)	1 / 21 (4.8)	NA	NA	NA	NA	NA	NA	NA
>= 65 years	0 / 2 (0.0)	0 / 3 (0.0)	NA	NA	NA	NA	NA	NA	NA
Sex									NA
Male	0 / 7 (0.0)	0 / 5 (0.0)	NA	NA	NA	NA	NA	NA	NA
Female	0 / 17 (0.0)	1 / 19 (5.3)	NA	NA	NA	NA	NA	NA	NA
Baseline steroid use									NA
Prednisone <= 20 mg/day	0 / 13 (0.0)	1 / 19 (5.3)	NA	NA	NA	NA	NA	NA	NA
Prednisone > 20 mg/day	0 / 10 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline QMG									NA
QMG <= 15	0 / 9 (0.0)	0 / 13 (0.0)	NA	NA	NA	NA	NA	NA	NA
QMG >= 16	0 / 15 (0.0)	1 / 9 (11.1)	NA	NA	NA	NA	NA	NA	NA
Baseline MGFA class									NA
II	0 / 12 (0.0)	1 / 13 (7.7)	NA	NA	NA	NA	NA	NA	NA
III	0 / 12 (0.0)	0 / 9 (0.0)	NA	NA	NA	NA	NA	NA	NA
IV	0 / 0 (-)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	0 / 15 (0.0)	1 / 14 (7.1)	NA	NA	NA	NA	NA	NA	NA
Europe	0 / 2 (0.0)	0 / 7 (0.0)	NA	NA	NA	NA	NA	NA	NA
North America	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Rest of the world	0 / 5 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
EU	0 / 2 (0.0)	0 / 7 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-EU	0 / 22 (0.0)	1 / 17 (5.9)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Japan	0 / 2 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	0 / 22 (0.0)	1 / 22 (4.5)	NA	NA	NA	NA	NA	NA	NA

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log. n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level. Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject). 95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios. If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.									

1.12.5 UE nach SOC/PT, die bei ≥ 10 % der Patientinnen und Patienten in einem der beiden Behandlungsarmen oder bei mindestens 10 Patientinnen und Patienten insgesamt und bei ≥ 1 % in einem der beiden Behandlungsarmen auftraten

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
AChR+ Population (Week 52)									
--no data to report--									
MuSK+ Population (Week 26)									
SOC: Erkrankungen des Nervensystems									
Age									NA
>= 18 - < 65 years	2 / 22 (9.1)	7 / 21 (33.3)	NA	NA	NA	NA	NA	NA	NA
>= 65 years	0 / 2 (0.0)	1 / 3 (33.3)	NA	NA	NA	NA	NA	NA	NA
Sex									NA
Male	1 / 7 (14.3)	3 / 5 (60.0)	NA	NA	NA	NA	NA	NA	NA
Female	1 / 17 (5.9)	5 / 19 (26.3)	NA	NA	NA	NA	NA	NA	NA
Baseline steroid use									NA
Prednisone <= 20 mg/day	2 / 13 (15.4)	7 / 19 (36.8)	NA	NA	NA	NA	NA	NA	NA
Prednisone > 20 mg/day	0 / 10 (0.0)	0 / 2 (0.0)	NA	NA	NA	NA	NA	NA	NA
Baseline QMG									NA
QMG <= 15	0 / 9 (0.0)	4 / 13 (30.8)	NA	NA	NA	NA	NA	NA	NA
QMG >= 16	2 / 15 (13.3)	3 / 9 (33.3)	NA	NA	NA	NA	NA	NA	NA
Baseline MGFA class									NA
II	1 / 12 (8.3)	3 / 13 (23.1)	NA	NA	NA	NA	NA	NA	NA
III	1 / 12 (8.3)	3 / 9 (33.3)	NA	NA	NA	NA	NA	NA	NA
IV	0 / 0 (-)	1 / 1 (100.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	1 / 15 (6.7)	3 / 14 (21.4)	NA	NA	NA	NA	NA	NA	NA
Europe	0 / 2 (0.0)	3 / 7 (42.9)	NA	NA	NA	NA	NA	NA	NA
North America	1 / 2 (50.0)	2 / 2 (100.0)	NA	NA	NA	NA	NA	NA	NA
Rest of the world	0 / 5 (0.0)	0 / 1 (0.0)	NA	NA	NA	NA	NA	NA	NA
Region									NA
EU	0 / 2 (0.0)	3 / 7 (42.9)	NA	NA	NA	NA	NA	NA	NA
Non-EU	2 / 22 (9.1)	5 / 17 (29.4)	NA	NA	NA	NA	NA	NA	NA

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
Region									NA
Japan	1 / 2 (50.0)	1 / 2 (50.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	1 / 22 (4.5)	7 / 22 (31.8)	NA	NA	NA	NA	NA	NA	NA

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level.
Coded using MedDRA version 23.0
95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

1.12.6 SUE nach SOC/PT, die bei ≥ 5 % der Patientinnen und Patienten in einem der beiden Behandlungsarmen oder bei mindestens 10 Patientinnen und Patienten insgesamt und bei ≥ 1 % in einem der beiden Behandlungsarmen auftraten

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
AChR+ Population (Week 52)									
--no data to report--									
MuSK+ Population (Week 26)									
--no data to report--									

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level.
Coded using MedDRA version 23.0
Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).
95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

1.12.7 Schwere UE (CTCAE Grad ≥ 3) nach SOC/PT, die bei ≥ 5 % der Patientinnen und Patienten in einem der beiden Behandlungsarmen oder bei mindestens 10 Patientinnen und Patienten insgesamt und bei ≥ 1 % in einem der beiden Behandlungsarmen auftraten

			Inebilizumab vs. Placebo						
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
Subgroup	n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
AChR+ Population (Week 52)									
--no data to report--									
MuSK+ Population (Week 26)									
--no data to report--									

Three duplicate steroid records were excluded from baseline dose calculation to fix data errors in EDC that caused overlapping of start and stop dates. The errors were identified after DBL and documented in the data errata log.
n = Number of subjects with observed data. N1 = Number of subjects in each subgroup level.
Coded using MedDRA version 23.0
95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.