The safety and efficacy of chronic weekly rozanolixizumab treatment in patients with generalized myasthenia gravis (MG0004)

AAN 2024, Denver, CO, USA; April 13–18, 2024

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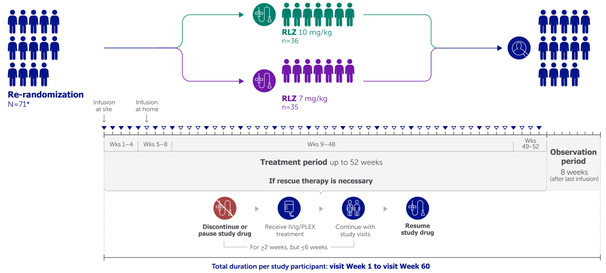
Introduction

- Rozanolixizumab is a humanized IgG4 mAb FcRn inhibitor approved by the US FDA for the treatment of adults with AChR Ab+ or MuSK Ab+ gMG[1,2]
- In the Phase 3, randomized, placebo-controlled MycarinG study (MG0003/NCT03971422), weekly SC rozanolixizumab 7 mg/kg or 10 mg/kg for a single 6-week cycle was generally well tolerated and provided clinically meaningful improvements in MG-specific outcomes in patients with gMG[1]
- Patients from MycarinG who completed the study or required rescue therapy during the observation period could enroll in MG0004 (NCT04124965), a Phase 3, multicenter, randomized, OLE study of weekly rozanolixizumab for up to 52 weeks

Methods

- Patients enrolled in MycarinG were aged ≥18 years with AChR Ab+ or MuSK Ab+ gMG[1]
  - Patients could enroll in MG0004 if they either completed MycarinG or required rescue therapy (IVIg or PLEX) during the observation period and opted to enter MG0004 and receive rozanolixizumab instead
- In MG0004, patients were re-randomized (1:1) to receive up to 52 once-weekly SC infusions of rozanolixizumab 7 mg/kg or 10 mg/kg, followed by an 8-week observation period (**Figure 1**)
  - Patients could switch dose at the investigator's discretion
  - After ≥6 visits, patients could roll over into MG0007 (NCT04650854), an OLE study of cyclic rozanolixizumab[3–5]
- Efficacy outcomes included CFB up to Week 60 in MG-ADL, MGC and QMG scores, CFB in total IgG and use of rescue therapy; analyses are presented by first dose received
- Safety variables were assessed for patients who received ≥1 rozanolixizumab dose; TEAEs are presented by most recent dose

Figure 1 MG0004 study design



*Patients could switch dose from 10 mg/kg to 7 mg/kg and vice versa at the investigator's discretion.

Results

Patients

- A total of 71 patients were re-randomized in MG0004, of whom 70 received ≥1 dose of rozanolixizumab 7 mg/kg (n=35) or 10 mg/kg (n=35)
- Baseline characteristics were generally balanced between dose groups (**Table 1**)
- Mean (SD) duration of rozanolixizumab treatment and number of infusions were:
  - 7 mg/kg: 22.9 (14.6) weeks; 21.7 (13.0) infusions
  - 10 mg/kg: 23.7 (14.6) weeks; 21.6 (12.3) infusions
- After Week 6, patients could transition to the MG0007 study; 17 (24.3%) patients remained in MG0004 at Week 33 and 8 (11.4%) patients completed 52 weeks of chronic weekly treatment
- In the 7 mg/kg group, 5/35 patients switched to 10 mg/kg, of whom 3 remained on the higher dose; in the 10 mg/kg group, 14/35 patients switched to 7 mg/kg, of whom 12 remained on the lower dose

Safety

- Overall, 85.7% (60/70) of patients reported ≥1 TEAE, with similar incidences across 7 mg/kg and 10 mg/kg (76.0% [38/50] and 78.6% [33/42], respectively) (**Table 2**)
  - The most common TEAEs were headache, diarrhea, decreased blood IgG, nausea, pyrexia and UTI
  - Most TEAEs were mild or moderate, with severe TEAEs reported in 24.0% of patients in the 7 mg/kg group and 11.9% in the 10 mg/kg group
- Serious TEAEs were reported in 14.0% (7/50) of patients in the 7 mg/kg group and 4.8% (2/42) in the 10 mg/kg group
  - The only serious TEAE reported in >1 patient was MG worsening (3 cases in 7 mg/kg; 1 case in 10 mg/kg)
  - No serious TEAEs were considered to be related to rozanolixizumab
- TEAEs leading to discontinuation of rozanolixizumab were reported in 6.0% (3/50) of patients in the 7 mg/kg group (MG [n=2] and congestive cardiac failure [n=1]) and no patients in the 10 mg/kg group
- Infections were reported in 26.0% (13/50) of patients in the 7 mg/kg group and 21.4% (9/42) of patients in the 10 mg/kg group
  - There were no serious, severe or opportunistic infections, and no infections led to study discontinuation
- No clinically relevant reductions in albumin were observed and no patients reported TEAEs related to albumin reductions
- There were no deaths

Efficacy

- Clinically relevant improvements in MG-ADL score were observed with rozanolixizumab treatment (**Figure 2a**)
  - CFB in MG-ADL score showed a stable trend up to Week 33, after which patient numbers were lower (≤10 per treatment group at any scheduled assessment); mean CFB was consistently greater in the 10 mg/kg group compared with the 7 mg/kg group up to Week 33
  - The maximum mean reduction from baseline up to Week 33 was –3.1 (Week 13) for the 7 mg/kg group and –4.1 (Week 21) for the 10 mg/kg group
  - A rapid decrease from baseline in MG-ADL score was observed at Week 5, the earliest time of assessment following treatment initiation, with a mean CFB of –2.7 in the 7 mg/kg group and –3.2 in the 10 mg/kg group
- Similar trends were observed in the CFB of MGC (**Figure 2b**) and QMG scores (**Figure 2c**)
- A rapid median decrease from baseline in total IgG of 48.0% in the 7 mg/kg group and 47.9% in the 10 mg/kg group was observed at Week 2
  - The median maximum reduction from baseline was 75.6% (n=32) and 79.9% (n=33), respectively
- Use of rescue therapy up to Week 60 was reported in 4 (11.4%) patients in the 7 mg/kg group (2 each during the treatment and observation periods) and no patients in the 10 mg/kg group; all received IVIg

Table 1 Baseline demographic and patient characteristics

		RLZ 7 mg/kg n=35	RLZ 10 mg/kg n=36	RLZ total N=71
	Age, years, mean (SD)	**50.6** (14.2)	**53.7** (17.2)	**52.2** (15.8)
	Sex, female, n (%)	**19** (54.3)	**19** (52.8)	**38** (53.5)
Geographic region, n (%)	North America	**16** (45.7)	**11** (30.6)	**27** (38.0)
	Europe	**15** (42.9)	**21** (58.3)	**36** (50.7)
	Asia (excl. Japan)	**0**	**2** (5.6)	**2** (2.8)
	Japan	**4** (11.4)	**2** (5.6)	**6** (8.5)
Race, n (%)	Asian	**4** (11.4)	**4** (11.1)	**8** (11.3)
	Black	**2** (5.7)	**3** (8.3)	**5** (7.0)
	White	**17** (48.6)	**19** (52.8)	**36** (50.7)
	Missing*	**12** (34.3)	**10** (27.8)	**22** (31.0)
	Thymectomy, yes, n (%)	**14** (40.0)	**15** (41.7)	**29** (40.8)
	Historical anti-AChR Ab+, n (%)	**30** (85.7)	**32** (88.9)	**62** (87.3)
	Historical anti-MuSK Ab+, n (%)	**5** (14.3)	**4** (11.1)	**9** (12.7)
	MG-ADL score, mean (SD)	**8.4** (3.6)	**8.4** (3.7)	**8.4** (3.6)
	QMG score, mean (SD)	**15.2** (5.1)	**15.4** (5.5)	**15.3** (5.3)
	Duration of disease, years, mean (SD)†	**8.7** (9.7)	**8.2** (8.4)	**8.5** (9.0)
Prior gMG medication, n (%)	Corticosteroids for systemic use	**24** (68.6)	**20** (55.6)	**44** (62.0)
	Immunosuppressants	**19** (54.3)	**18** (50.0)	**37** (52.1)
	Parasympathomimetics	**30** (85.7)	**30** (83.3)	**60** (84.5)

Randomized set; 1 patient was not treated and was not included in the safety set.
*Data on race were not permitted to be collected in France and Canada.
†Data obtained at MG0003 baseline.

Table 2 Overview of TEAEs

	Patients experiencing TEAEs, n (%)		
	RLZ 7 mg/kg n=50*	RLZ 10 mg/kg n=42*	RLZ total N=70
Any TEAEs[†]	**38** (76.0)	**33** (78.6)	**60** (85.7)
Headache	**15** (30.0)	**12** (28.6)	**25** (35.7)
Diarrhea	**6** (12.0)	**7** (16.7)	**13** (18.6)
Decreased blood IgG	**6** (12.0)	**5** (11.9)	**11** (15.7)
Nausea	**4** (8.0)	**5** (11.9)	**9** (12.9)
Pyrexia	**4** (8.0)	**3** (7.1)	**7** (10.0)
UTI	**5** (10.0)	**2** (4.8)	**7** (10.0)
Serious TEAEs	**7** (14.0)	**2** (4.8)	**9** (12.9)
Permanent discontinuation from study due to TEAEs	**4** (8.0)	**0**	**4** (5.7)
Permanent discontinuation of study drug due to TEAEs	**3** (6.0)[‡]	**0**	**3** (4.3)[‡]
TEAEs requiring dose change	**0**	**1** (2.4)	**1** (1.4)
Treatment-related TEAEs	**25** (50.0)	**18** (42.9)	**41** (58.6)
Severe TEAEs[§]	**12** (24.0)	**5** (11.9)	**17** (24.3)
Headache	**3** (6.0)	**2** (4.8)	**5** (7.1)
MG	**2** (4.0)	**1** (2.4)	**3** (4.3)
All deaths (AEs leading to death)	**0**	**0**	**0**

Safety set.
*Participants who switched doses may be counted in both RLZ treatment groups but only once in the RLZ total group.
†Specific TEAEs listed are those occurring in ≥10% of patients overall.
‡MG (n=2) and congestive cardiac failure (n=1).
§Specific severe TEAEs listed are those occurring in >1 patient overall.

Summary and conclusions

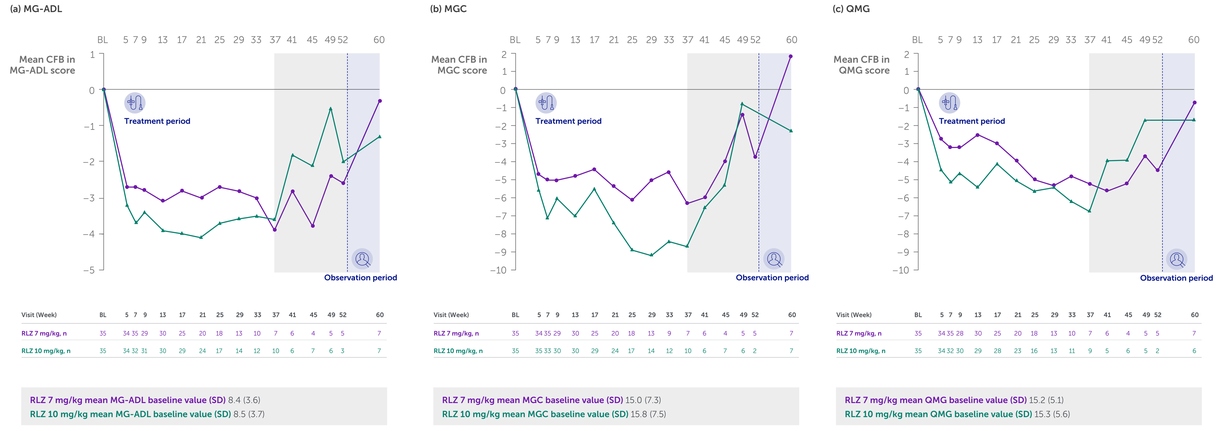
MG0004 was a Phase 3, multicenter, randomized, OLE study of chronic weekly rozanolixizumab treatment for up to 52 weeks in patients with gMG

Chronic weekly rozanolixizumab was generally well tolerated, with a safety profile similar to repeated cycles of rozanolixizumab treatment[5]

Clinically relevant mean improvements were maintained across MG-specific outcomes up to Week 33; patient numbers were low after Week 33

The MG0004 study further supports the long-term safety, tolerability and efficacy of rozanolixizumab in patients with AChR Ab+ or MuSK Ab+ gMG

Figure 2 Mean CFB in MG-ADL, MGC, and QMG scores



Safety set. The gray area represents study visits at which patient numbers were low (≤10 per treatment group at any scheduled assessment).

Abbreviations: Ab+, autoantibody positive; AChR, acetylcholine receptor; AE, adverse event; BL, baseline; CFB, change from baseline; FcRn, neonatal Fc receptor; FDA, Food and Drug Administration; gMG, generalized myasthenia gravis; IgG, immunoglobulin G; IVIg, intravenous immunoglobulin; mAb, monoclonal antibody; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGC, Myasthenia Gravis Composite; MuSK, muscle-specific tyrosine kinase; OLE, open-label extension; PLEX, plasma exchange; QMG, Quantitative Myasthenia Gravis; RLZ, rozanolixizumab; SC, subcutaneous; SD, standard deviation; TEAE, treatment-emergent adverse event; UTI, urinary tract infection; Wks, weeks.

Acknowledgments: This study was funded by UCB Pharma. The authors acknowledge Alpa Parmar, PhD, CMPP, and Jenny Fanstone of Ogilvy Health, London, UK, for editorial support in the form of writing, drafting tables and figures, collating author comments, and editorial assistance, which was funded by UCB Pharma. The authors acknowledge Veronica Porkess, PhD, of UCB Pharma, Slough, UK, for publication coordination. The authors thank the patients and their caregivers, in addition to the investigators and their teams who contributed to this study.

Author disclosures: Vera Bril is a Consultant for Alxcea, Alexion Pharmaceuticals, Alnylam, argenx, CSL, Grifols, Ionis, Immunovant, Janssen Pharmaceuticals, Momenta (now Johnson and Johnson), Novo Nordisk, Octapharma, Pfizer, Powell Mansfield, Sanofi, Takeda, Roche and UCB Pharma. She has received research support from Alxcea, Alexion Pharmaceuticals, argenx, CSL, Grifols, Immunovant, Ionis, Momenta (now Johnson and Johnson), Octapharma, Takeda, UCB Pharma and Viela Bio (now Horizon Therapeutics). Artur Drużdż and Sabrina Sacconi have nothing to disclose. Julian Grosskreutz has served as a Consultant for Biogen, Alexion Pharmaceuticals, and UCB Pharma, and his institution has received research support from the Boris Canessa Foundation. Ali A. Habib has received research support from Alexion Pharmaceuticals, argenx, Cabaletta Bio, Genentech/Roche, Immunovant, Regeneron Pharmaceuticals, UCB Pharma and Viela Bio (now Horizon Therapeutics). He has received honoraria from Alexion Pharmaceuticals, Alpine Immune Sciences, argenx, Genentech/Roche, Immunovant, Inhibrx, Regeneron Pharmaceuticals, NMD Pharma and UCB Pharma. Henry J. Kaminski is a Consultant for Roche, Cabaletta Bio, Lincoln Therapeutics, Takeda, and UCB Pharma and is CEO and CMO of ARC Biotechnology, LLC based on US Patent 8,961,98. He is Principal Investigator of the Rare Disease Network for Myasthenia Gravis (MGNet) National Institute of Neurological Disorders & Stroke, U54 NS115054, and Targeted Therapy for Myasthenia Gravis. He has received R41 NS110331-01 to ARC Biotechnology. Renato Mantegazza has received funding for travel and meeting attendance or advisory board participation from Alexion Pharmaceuticals, argenx, BioMarin, Catalyst, Sanofi, Regeneron Pharmaceuticals, and UCB Pharma. Kimiaki Utsugisawa has served as a paid Consultant for UCB Pharma, argenx, Janssen Pharmaceuticals, Viela Bio (now Horizon Therapeutics), Chugai Pharmaceutical, Hankil Biopharma, Merck and Mitubishi Tanabe Pharma; he has received speaker honoraria from argenx, Alexion Pharmaceuticals, UCB Pharma, and the Japan Blood Products Organization. Tuan Vu is the USF Site Principal Investigator for MG clinical trials sponsored by Alexion Pharmaceuticals/AstraZeneca, Amgen, argenx, Cartesian Therapeutics, Dianthus, Immunovant, Johnson and Johnson, Regeneron, RemeGen and UCB Pharma. He has served as a speaker for Alexion Pharmaceuticals, Allergan/Abbvie, argenx and CSL Behring. He has performed consulting work for Alexion Pharmaceuticals/AstraZeneca, argenx, Dianthus, ImmunoAbs, RemeGen and UCB Pharma Marion Boehnlein, Franz Woltering, Bernhard Greve and Maryam Gayfieva are employees and shareholders of UCB Pharma. John Vissing has been a Consultant on advisory boards for Amicus Therapeutics, Arvinas, Biogen, Fulcrum Therapeutics, Genethon, Horizon Therapeutics, Lupin, Mi, Biopharma, Novartis Pharma AG, Regeneron, Roche, Sanofi Genzyme, Sarepta Therapeutics and UCB Pharma. He has received research, travel support and/or speaker honoraria from Alexion Pharmaceuticals, argenx, Biogen, Edgewise Therapeutics, Fulcrum Therapeutics, Lupin, Sanofi Genzyme and UCB Pharma. He is a Principal Investigator in clinical trials for Alexion Pharmaceuticals, argenx, Genethon, Horizon Therapeutics, Janssen Pharmaceuticals, Mi, Biopharma, Novartis Pharma, Regeneron, Roche, Sanofi-Genzyme and UCB Pharma.

References: 1. Bril V, et al. Lancet Neurol. 2023;22:383–394. 2. Rystiggo® US PI. https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf. Accessed March 2024. 3. Bril V, et al. Long-term efficacy and safety of symptom-driven cyclical rozanolixizumab treatment in patients with generalized myasthenia gravis: a pooled analysis of a Phase 3 study and two open-label extension studies [poster]. AAN 2023. Poster P1-5-012. 4. Vissing J, et al. Rozanolixizumab responder and minimal symptom expression rates in generalized MG: pooled Phase 3 and extension studies [poster]. EAN 2023. Poster EPO-412. 5. Vu T, et al. Long-term safety of repeated cycles of rozanolixizumab treatment in patients with generalized myasthenia gravis [poster]. AANEM 2023. Poster 269.

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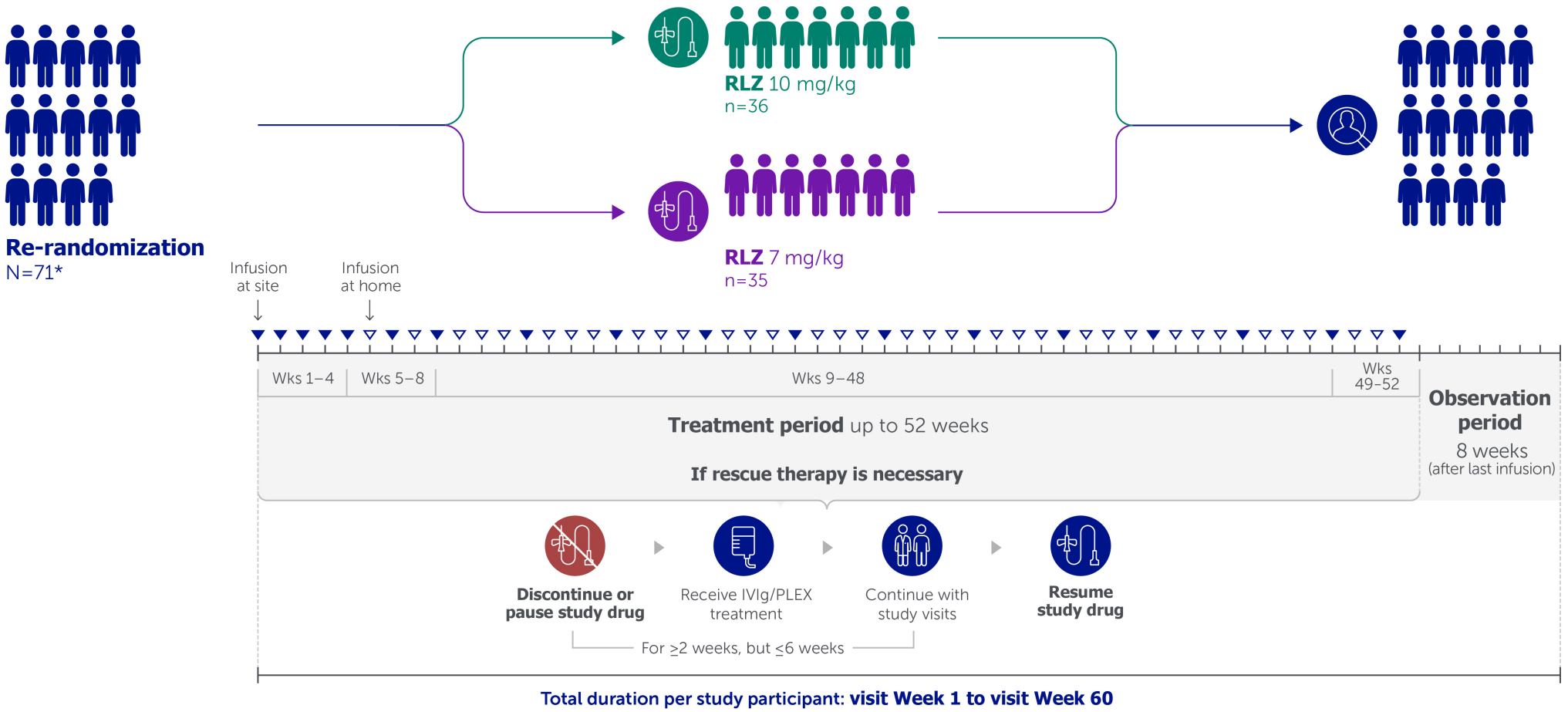
Figure 1 MG0004 study design



*Patients could switch dose from 10 mg/kg to 7 mg/kg and vice versa at the investigator's discretion.
IVIg, intravenous immunoglobulin; PLEX, plasma exchange; RLZ, rozanolixizumab.

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	Japan	**4** (11.4)	**2** (5.6)	**6** (8.5)
Race, n (%)	Asian	**4** (11.4)	**4** (11.1)	**8** (11.3)
	Black	**2** (5.7)	**3** (8.3)	**5** (7.0)
	White	**17** (48.6)	**19** (52.8)	**36** (50.7)
	Missing*	**12** (34.3)	**10** (27.8)	**22** (31.0)
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	Historical anti-AChR Ab+, n (%)	**30** (85.7)	**32** (88.9)	**62** (87.3)
	Historical anti-MuSK Ab+, n (%)	**5** (14.3)	**4** (11.1)	**9** (12.7)
	MG-ADL score, mean (SD)	**8.4** (3.6)	**8.4** (3.7)	**8.4** (3.6)
	QMG score, mean (SD)	**15.2** (5.1)	**15.4** (5.5)	**15.3** (5.3)
	Duration of disease, years, mean (SD)†	**8.7** (9.7)	**8.2** (8.4)	**8.5** (9.0)
Prior gMG medication, n (%)	Corticosteroids for systemic use	**24** (68.6)	**20** (55.6)	**44** (62.0)
	Immunosuppressants	**19** (54.3)	**18** (50.0)	**37** (52.1)
	Parasympathomimetics	**30** (85.7)	**30** (83.3)	**60** (84.5)

Randomized set; 1 patient was not treated and was not included in the safety set.
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Ab+, autoantibody positive; AChR, acetylcholine receptor; gMG, generalized myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MuSK, muscle-specific tyrosine kinase; QMG, Quantitative Myasthenia Gravis; RLZ, rozanolixizumab; SD, standard deviation.

Table 2 Overview of TEAEs

	Patients experiencing TEAEs, n (%)		
	RLZ 7 mg/kg n=50*	RLZ 10 mg/kg n=42*	RLZ total N=70
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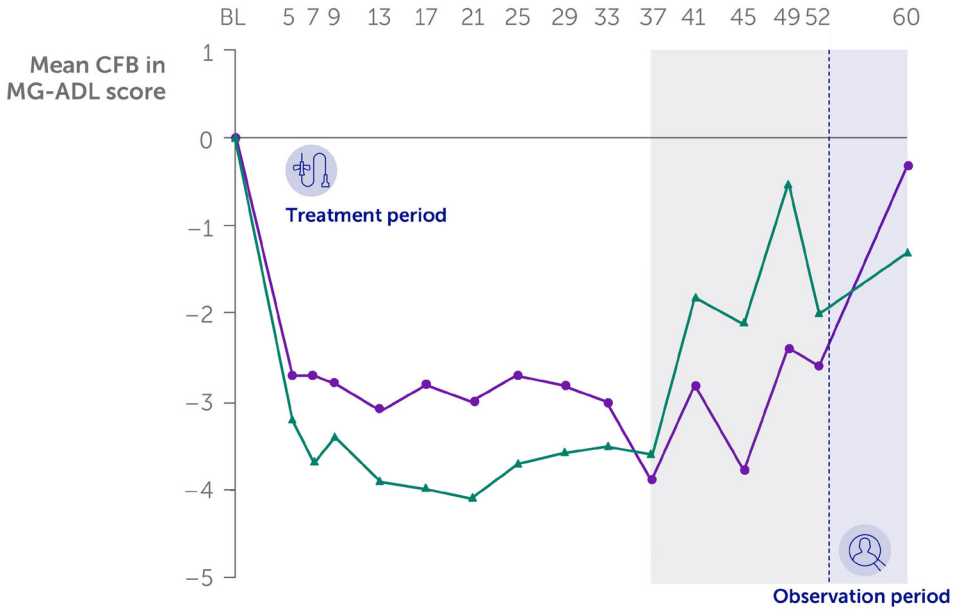
Diarrhea	**6** (12.0)	**7** (16.7)	**13** (18.6)
Decreased blood IgG	**6** (12.0)	**5** (11.9)	**11** (15.7)
Nausea	**4** (8.0)	**5** (11.9)	**9** (12.9)
Pyrexia	**4** (8.0)	**3** (7.1)	**7** (10.0)
UTI	**5** (10.0)	**2** (4.8)	**7** (10.0)
Serious TEAEs	**7** (14.0)	**2** (4.8)	**9** (12.9)
Permanent discontinuation from study due to TEAEs	**4** (8.0)	**0**	**4** (5.7)
Permanent discontinuation of study drug due to TEAEs	**3** (6.0)[‡]	**0**	**3** (4.3)[‡]
TEAEs requiring dose change	**0**	**1** (2.4)	**1** (1.4)
Treatment-related TEAEs	**25** (50.0)	**18** (42.9)	**41** (58.6)
Severe TEAEs[§]	**12** (24.0)	**5** (11.9)	**17** (24.3)
Headache	**3** (6.0)	**2** (4.8)	**5** (7.1)
MG	**2** (4.0)	**1** (2.4)	**3** (4.3)
All deaths (AEs leading to death)	**0**	**0**	**0**

Safety set.
*Participants who switched doses may be counted in both RLZ treatment groups but only once in the RLZ total group.
[†]Specific TEAEs listed are those occurring in ≥10% of patients overall.
[‡]MG (n=2) and congestive cardiac failure (n=1).
[§]Specific severe TEAEs listed are those occurring in >1 patient overall.
AE, adverse event; IgG, immunoglobulin G; MG, myasthenia gravis; RLZ, rozanolixizumab; TEAE, treatment-emergent adverse event; UTI, urinary tract infection.

Figure 2 Mean CFB in MG-ADL, MGC, and QMG scores

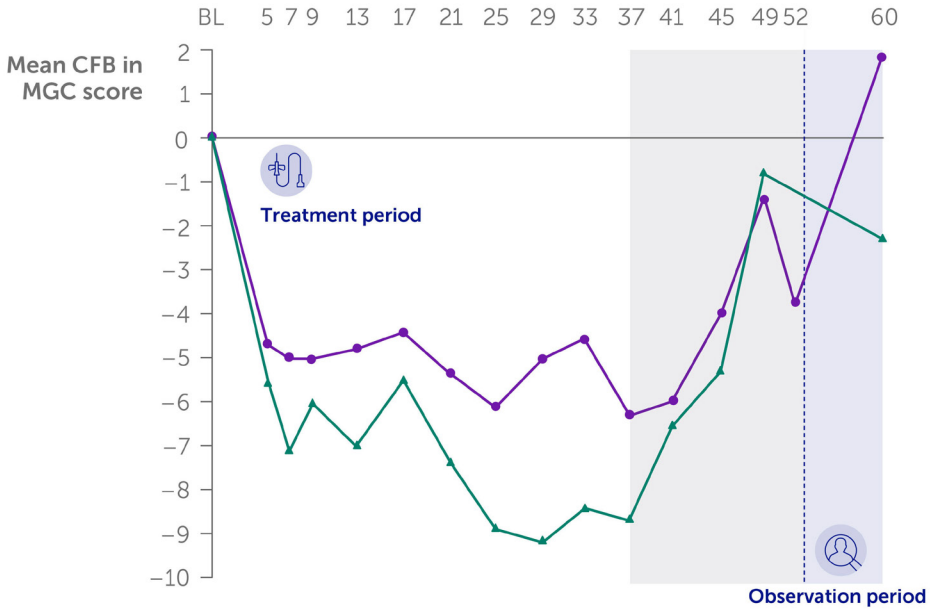
a) MG-ADL



Visit (Week)	BL	5	7	9	13	17	21	25	29	33	37	41	45	49	52	60
RLZ 7 mg/kg, n	35	34	35	29	30	25	20	18	13	10	7	6	4	5	5	7
RLZ 10 mg/kg, n	35	34	32	31	30	29	24	17	14	12	10	6	7	6	3	7

RLZ 7 mg/kg mean MG-ADL baseline value (SD) 8.4 (3.6)
RLZ 10 mg/kg mean MG-ADL baseline value (SD) 8.5 (3.7)

b) MGC



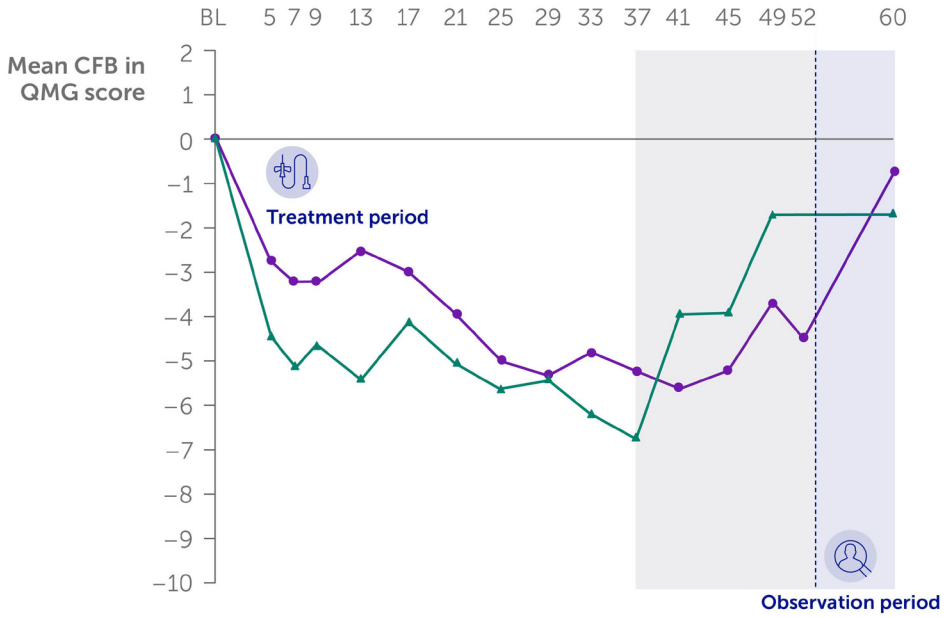
Visit (Week)	BL	5	7	9	13	17	21	25	29	33	37	41	45	49	52	60
RLZ 7 mg/kg, n	35	34	35	29	30	25	20	18	13	9	7	6	4	5	5	7
RLZ 10 mg/kg, n	35	35	33	30	30	29	24	17	14	12	10	6	7	6	2	7

RLZ 7 mg/kg mean MGC baseline value (SD) 15.0 (7.3)
RLZ 10 mg/kg mean MGC baseline value (SD) 15.8 (7.5)

Safety set. The gray area represents study visits at which patient numbers were low (≤10 per treatment group at any scheduled assessment).
BL, baseline; CFB, change from baseline; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGC, Myasthenia Gravis Composite; QMG, Quantitative Myasthenia Gravis; RLZ, rozanolixizumab.

Figure 2 Mean CFB in MG-ADL, MGC, and QMG scores

c) QMG



Visit (Week)	BL	5	7	9	13	17	21	25	29	33	37	41	45	49	52	60
RLZ 7 mg/kg, n	35	34	35	28	30	25	20	18	13	10	7	6	4	5	5	7
RLZ 10 mg/kg, n	35	34	32	30	29	28	23	16	13	11	9	5	6	5	2	6

RLZ 7 mg/kg mean QMG baseline value (SD) 15.2 (5.1)
RLZ 10 mg/kg mean QMG baseline value (SD) 15.3 (5.6)

Safety set. The gray area represents study visits at which patient numbers were low (≤10 per treatment group at any scheduled assessment).
BL, baseline; CFB, change from baseline; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGC, Myasthenia Gravis Composite; QMG, Quantitative Myasthenia Gravis; RLZ, rozanolixizumab.

Summary and conclusions

MG0004 was a Phase 3, multicenter, randomized, OLE study of chronic weekly rozanolixizumab treatment for up to 52 weeks in patients with gMG

Chronic weekly rozanolixizumab was generally well tolerated, with a safety profile similar to repeated cycles of rozanolixizumab treatment[1]

Clinically relevant mean improvements were maintained across MG-specific outcomes up to Week 33; patient numbers were low after Week 33

The MG0004 study further supports the long-term safety, tolerability and efficacy of rozanolixizumab in patients with AChR Ab+ or MuSK Ab+ gMG

1. Vu T, et al. Long-term safety of repeated cycles of rozanolixizumab treatment in patients with generalized myasthenia gravis [poster]. AANEM 2023. Poster 269.

Ab+, autoantibody positive; AChR, acetylcholine receptor; gMG, generalized myasthenia gravis; MG, myasthenia gravis; MuSK, muscle-specific tyrosine kinase; OLE, open-label extension.