Effect of repeated cycles of rozanolixizumab on myasthenia gravis-specific outcome subdomain scores: A *post hoc* analysis of final Phase 3 and OLE data

ACKNS 2026, Dallas, TX, USA; February 19–20, 2026

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Introduction

- Fluctuating muscle weakness is a manifestation of gMG and different muscle groups may respond to treatment differently[1–4]
- Rozanolixizumab is a humanized IgG4 mAb that targets and blocks FcRn with high affinity, and is approved for the treatment of adults with anti-AChR Ab+ or anti-MuSK Ab+ gMG[5,6]
- In the randomized, double-blind, Phase 3 MycarinG study (NCT03971422), one 6-week cycle of rozanolixizumab (7 mg/kg or 10 mg/kg) demonstrated clinically meaningful improvements in MG-specific outcomes versus placebo in patients with gMG[5]
  - Following MycarinG, patients could enroll in open-label extension studies MG0004 (NCT04124965) then MG0007 (NCT04650854), or MG0007 directly[7]
- **This analysis evaluated the effect of long-term, cyclic rozanolixizumab treatment on MG-ADL and QMG subdomain scores assessing ocular, bulbar, respiratory, and limb weakness/gross motor muscle groups**

Methods

- MycarinG enrolled adults with MGFA Disease Class II–IVa anti-AChR Ab+ or anti-MuSK Ab+ gMG with an MG-ADL score ≥3 (for non-ocular symptoms) and a QMG score ≥11
  - Patients received rozanolixizumab or placebo once weekly for 6 weeks (one cycle)
- Final efficacy data were pooled across MycarinG, MG0004 (first 6 weeks) and MG0007 for patients with ≥2 symptom-driven cycles
- Mean MG-ADL and QMG subdomain scores and percentage change in severity rates across Cycles 1–13 were assessed *post hoc* using a weighted mean approach accounting for varying sample size per cycle
- Final safety data were pooled across MycarinG and MG0007 for patients with ≥1 treatment cycle; incidence of TEAEs was assessed

Results

- Overall, 196 patients received ≥1 dose of rozanolixizumab, of whom:
  - 129 received ≥2 symptom-driven cycles (primary efficacy pool)
  - 188 received ≥1 treatment cycle with rozanolixizumab (primary safety pool)
- Baseline characteristics were similar between the primary efficacy and safety pools, balanced between the 7 mg/kg and 10 mg/kg groups, and were indicative of a population with moderate-to-severe gMG
- Consistent improvements from baseline in MG-ADL scores at Day 43 were observed across 13 cycles for all four subdomains, with similar improvements for QMG (**Table 1**)
  - Reductions were observed in weighted mean scores (calculated across all 13 cycles) in MG-ADL and QMG subdomains (**Figure 1**)
- Across Cycles 1–13 (weighted average), the percentages of patients who improved to no symptoms in each MG-ADL subdomain at Day 43 was greatest for the bulbar subdomain at 35.4%, followed by axial (28.1%), ocular (24.9%) and respiratory (22.7%) (**Figure 2**)
- Overall, 175/188 (93.1%) patients experienced any TEAE; most events were mild or moderate
  - The incidence of TEAEs did not increase with repeated cyclic treatment

Figure 1 Weighted mean MG-ADL and QMG scores

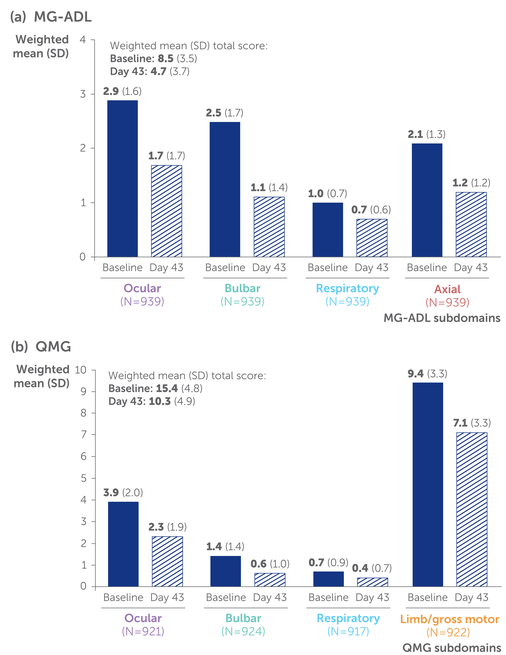
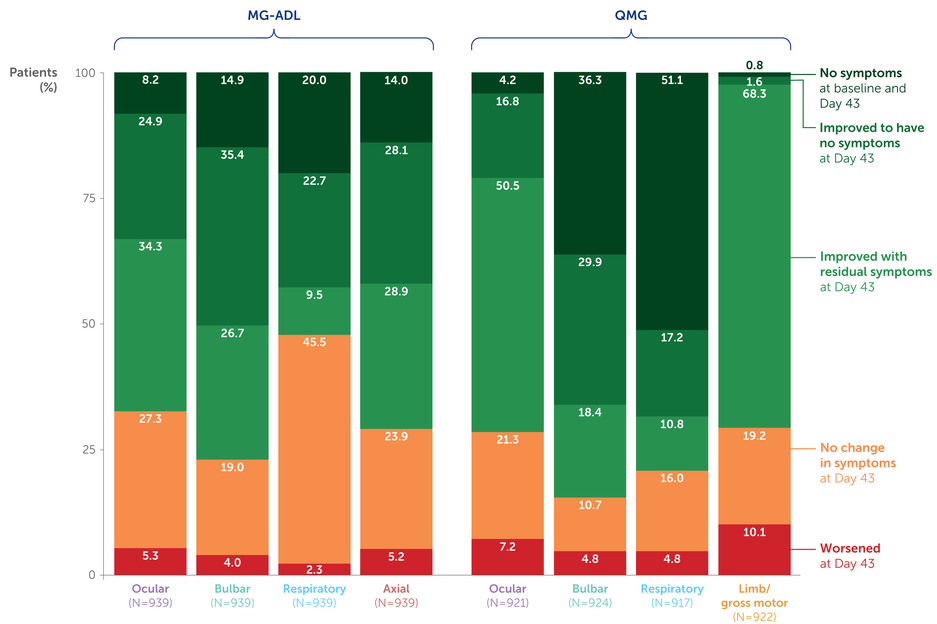


Figure 2 Most patients had improved MG-ADL and QMG subdomain scores across cycles 1–13



Summary and conclusions

Pooled data from the MycarinG and open-label extension studies provide insights into the efficacy and safety of rozanolixizumab over multiple symptom-driven cycles in patients with gMG

Long-term rozanolixizumab treatment led to improvements across all MG-ADL and QMG subdomain scores in patients with gMG

Rozanolixizumab had an acceptable safety profile and was generally well tolerated

These data support long-term use of rozanolixizumab across a broad range of signs and symptoms experienced by patients with gMG

Table 1 Reductions from baseline in MG-ADL and QMG scores were observed at Day 43 with rozanolixizumab across all four subdomains and across all cycles

MG-ADL	Cycle	1	2	3	4	5	6	7	8	9	10	11	12	13
Ocular Score range: 0–6	Mean CFB	**−1.0**	**−1.2**	**−1.0**	**−1.0**	**−1.2**	**−1.4**	**−1.0**	**−1.1**	**−1.0**	**−1.1**	**−1.1**	**−1.8**	**−1.2**
	(SD)	(1.4)	(1.4)	(1.3)	(1.4)	(1.4)	(1.4)	(1.4)	(1.5)	(1.4)	(1.6)	(1.4)	(1.5)	(1.7)
	n	129	129	113	98	88	81	70	62	51	44	33	24	17
Bulbar Score range: 0–9	Mean CFB	**−1.4**	**−1.4**	**−1.1**	**−1.4**	**−1.4**	**−1.5**	**−1.3**	**−1.4**	**−1.4**	**−1.1**	**−1.8**	**−2.0**	**−2.2**
	(SD)	(1.6)	(1.6)	(1.5)	(1.6)	(1.6)	(1.7)	(1.4)	(1.7)	(1.9)	(1.5)	(1.8)	(1.7)	(1.6)
	n	129	129	113	98	88	81	70	62	51	44	33	24	17
Respiratory Score range: 0–3	Mean CFB	**−0.3**	**−0.4**	**−0.2**	**−0.2**	**−0.3**	**−0.3**	**−0.4**	**−0.3**	**−0.5**	**−0.4**	**−0.4**	**−0.7**	**−0.6**
	(SD)	(0.6)	(0.6)	(0.6)	(0.6)	(0.5)	(0.5)	(0.5)	(0.6)	(0.7)	(0.7)	(0.6)	(0.7)	(0.7)
	n	129	129	113	98	88	81	70	62	51	44	33	24	17
Axial Score range: 0–6	Mean CFB	**−1.0**	**−0.9**	**−0.8**	**−0.9**	**−0.9**	**−1.1**	**−1.0**	**−1.0**	**−0.9**	**−0.9**	**−1.3**	**−1.5**	**−1.1**
	(SD)	(1.2)	(1.2)	(1.3)	(1.2)	(1.1)	(1.1)	(1.1)	(1.2)	(1.1)	(1.0)	(1.4)	(1.5)	(1.2)
	n	129	129	113	98	88	81	70	62	51	44	33	24	17

QMG	Cycle	1	2	3	4	5	6	7	8	9	10	11	12	13
Ocular Score range: 0–9	Mean CFB	**−1.5**	**−1.6**	**−1.5**	**−1.5**	**−1.3**	**−1.8**	**−2.1**	**−1.7**	**−1.6**	**−1.5**	**−1.7**	**−2.2**	**−1.6**
	(SD)	(1.8)	(2.0)	(2.0)	(1.9)	(2.0)	(1.9)	(2.0)	(1.8)	(2.1)	(1.9)	(1.7)	(1.8)	(2.0)
	n	129	125	110	97	85	79	68	61	50	43	33	24	17
Bulbar Score range: 0–6	Mean CFB	**−0.9**	**−0.9**	**−0.7**	**−0.8**	**−0.7**	**−0.9**	**−1.1**	**−0.7**	**−0.7**	**−0.7**	**−0.9**	**−0.9**	**−1.2**
	(SD)	(1.3)	(1.3)	(1.2)	(1.3)	(1.3)	(1.3)	(1.3)	(1.2)	(1.3)	(1.0)	(1.5)	(0.9)	(1.1)
	n	129	127	111	97	86	78	68	61	50	43	33	24	17
Respiratory Score range: 0–3	Mean CFB	**−0.2**	**−0.2**	**−0.3**	**−0.2**	**−0.2**	**−0.2**	**−0.4**	**−0.4**	**−0.4**	**−0.4**	**−0.5**	**−0.5**	**−0.4**
	(SD)	(0.7)	(0.6)	(0.7)	(0.6)	(0.7)	(0.7)	(0.7)	(0.7)	(0.7)	(0.7)	(0.8)	(0.7)	(0.7)
	n	129	127	111	97	85	77	66	60	50	42	33	24	16
Limb/gross motor Score range: 0–21	Mean CFB	**−2.8**	**−1.9**	**−2.3**	**−2.3**	**−2.5**	**−2.7**	**−2.4**	**−1.9**	**−2.2**	**−2.2**	**−2.6**	**−2.3**	**−2.2**
	(SD)	(3.0)	(2.9)	(2.6)	(2.9)	(2.9)	(2.8)	(2.7)	(2.6)	(2.7)	(3.1)	(2.9)	(2.3)	(2.3)
	n	129	127	110	97	86	78	68	60	50	43	33	24	17

Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; CFB, change from baseline; FcRn, neonatal fragment crystallizable receptor; gMG, generalized myasthenia gravis; IgG4, immunoglobulin G4; mAb, monoclonal antibody; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MuSK, muscle-specific tyrosine kinase; OLE, open-label extension; QMG, Quantitative Myasthenia Gravis; SD, standard deviation; TEAE, treatment-emergent adverse event.

Acknowledgments: This study was funded by UCB. The authors acknowledge Qudsia Ehsan, BSc, of Ogilvy Health, London, UK, for editorial assistance, which was funded by UCB. The authors thank Veronica Porkess, PhD, of UCB for publication and editorial support. The authors thank the patients and their caregivers, in addition to the investigators and their teams who contributed to this study.

Author disclosures: Thomas Wallace, Jos Bloemers, Paul Mahoney and Thaïs Tarancón are employees and shareholders of UCB. Zabeen K. Mahuwala has received compensation for advisory board participation from Alexion Pharmaceuticals and Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine) and has served as a panellist for Academic CME. She has received research funding for clinical trials paid to the University of Kentucky from Alexion Pharmaceuticals, argenx, Immunovant, Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine), RemeGen Biosciences and UCB. Ali A. Habib has received research support and/or honoraria from Alexion/AstraZeneca Rare Disease, Amgen, Arcelix, argenx, Cabaletta Bio, Cartesian Therapeutics, COUR Pharmaceuticals, Genentech/Roche, Grifols, Immunovant, Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine), Kyverna, Merck, MGNet, Nkarta, NMD Pharma, Novartis, Regeneron Pharmaceuticals and UCB. Robert M. Pascuzzi is Professor Emeritus of Neurology at Indiana University and receives compensation for his professional work from Indiana University Health. He has no financial relationship with any pharmaceutical company and receives no compensation from any pharmaceutical company (present or past). Robert M. Pascuzzi speaks at educational seminars on a broad variety of general neurology topics for primary care physicians through the organisation Medical Education Resources (an educational organisation with no links or ties to any pharmaceutical or healthcare business company). Therefore, Robert M. Pascuzzi has no conflicts of interest related to this research, manuscript, presentation, or publication. John Vissing has been a Consultant on advisory boards for Amicus Therapeutics, Biogen, Edgewise Therapeutics, Fulcrum Therapeutics, Genethon, Horizon Therapeutics (now Amgen), Lupin, ML Biopharma, Novartis, Regeneron Pharmaceuticals, Roche, Sanofi Genzyme (now Sanofi), Sarepta Therapeutics and UCB. He has received research and travel support and/or speaker honoraria from Alexion Pharmaceuticals, argenx, Biogen, Edgewise Therapeutics, Fulcrum Therapeutics, Lupin, Sanofi Genzyme (now Sanofi) and UCB. He is a Principal Investigator in clinical trials for Alexion Pharmaceuticals, argenx, Atamyo Therapeutics, Genethon, Horizon Therapeutics (now Amgen), Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine), ML Biopharma, Novartis, Regeneron Pharmaceuticals, Roche, Sanofi Genzyme (now Sanofi) and UCB. Tuan Vu is the USF Site Principal Investigator for MG clinical trials sponsored by Alexion/AstraZeneca Rare Disease, Amgen, argenx, Cartesian Therapeutics, COUR Pharmaceuticals, Dianthus Therapeutics, ImmunoAbs, Immunovant, Johnson & Johnson, NMD Pharma, Regeneron Pharmaceuticals, UCB and VOR, and has served as a speaker for Alexion/AstraZeneca Rare Disease, Amgen, argenx and CSL Behring. He has performed consulting work for Alexion/AstraZeneca Rare Disease, argenx, Dianthus Therapeutics, NMD Pharma, Regeneron and VOR. Vera Bril is a Consultant for Alcea, Alexion Pharmaceuticals, Alnylam, argenx, CSL, Grifols, Immunovant, Ionis, Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine), Momenta (now Johnson & Johnson), Novo Nordisk, Octapharma, Pfizer, Powell Mansfield, Roche, Sanofi, Takeda Pharmaceuticals and UCB. She has received research support from Alcea, Alexion Pharmaceuticals, argenx, CSL, Grifols, Immunovant, Ionis, Momenta (now Johnson & Johnson), Octapharma, Takeda Pharmaceuticals, UCB and Viela Bio (now Amgen).

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