Effect of rozanolixizumab on MG-ADL and QMG items: A *post hoc* Phase 3 final pooled analysis

Suraj Muley[1], Elena Cortés Vicente[2], Artur Drużdż[3], Laura Fionda[4,5], Ali A. Habib[6], Zabeen K. Mahuwala[7], Renato Mantegazza[8], Robert M. Pascuzzi[9], Sabrina Sacconi[10], Kimiaki Utsugisawa[11], John Vissing[12], Tuan Vu[13], Jos Bloemers[14], Paul Mahoney[15], Thaïs Tarancón[16] and Vera Bril[17]*

[1]John Shufeldt School of Medicine and Medical Engineering, Arizona State University, Phoenix, AZ, USA; [2]Neuromuscular Diseases Unit, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; [3]Department of Neurology, Municipal Hospital, Poznań, Poland; [4]Neuromuscular and Rare Disease Centre, UOC Neurologia, Sant'Andrea Hospital, Rome, Italy; [5]Department of Neurology, Mental Health and Sensory Organs (NESMOS), Faculty of Medicine and Psychology, Sapienza University of Rome, Rome, Italy; [6]MDA ALS & Neuromuscular Center, Department of Neurology, University of California, Irvine, Orange, CA, USA; [7]Department of Neuromuscular Medicine, Epilepsy and Clinical Neurophysiology, University of Kentucky, Lexington, KY, USA; [8]Emeritus and Past Director, Department of Neuroimmunology and Neuromuscular Diseases, Fondazione IRCCS, Istituto Neurologico Carlo Besta, Milan, Italy; [9]Neurology Department, Indiana University School of Medicine, Indiana University Health, Indianapolis, IN, USA; [10]Université Côte d'Azur, Peripheral Nervous System & Muscle Department, Pasteur 2 Hospital, Centre Hospitalier Universitaire de Nice, Nice, France; [11]Department of Neurology, Hanamaki General Hospital, Hanamaki, Japan; [12]Copenhagen Neuromuscular Center, Department of Neurology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; [13]Department of Neurology, University of South Florida Morsani College of Medicine, Tampa, FL, USA; [14]UCB, Breda, The Netherlands; [15]UCB, Slough, UK; [16]UCB, Madrid, Spain; [17]Ellen and Martin Prosserman Centre for Neuromuscular Diseases, Toronto General Hospital, University of Toronto, Toronto, Ontario, Canada

AANEM 2026, Orlando, FL, USA; September 29–October 2, 2026

Introduction

- gMG is a chronic, autoimmune, neuromuscular disease that is characterized by fluctuating muscle weakness, with treatment responses varying across different muscle groups[1–3]
- Rozanolixizumab, a humanized IgG4 mAb that targets and blocks FcRn with high affinity, is approved for the treatment of adults with anti-AChR Ab+ or anti-MuSK Ab+ gMG[4,5]
- In the randomized, double-blind, placebo-controlled, Phase 3 MycarinG study (NCT03971422), one 6-week cycle of rozanolixizumab 7 mg/kg or 10 mg/kg improved MG-ADL and QMG total scores compared with placebo in patients with gMG[6]
- **This *post hoc* analysis investigated the effect of repeated rozanolixizumab treatment cycles on MG-ADL and QMG individual item scores, using final pooled data from the extension studies**

Methods

- In MycarinG, patients were aged ≥18 years with MGFA Clinical 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
- Following MycarinG, patients could enroll in OLE studies MG0004 (NCT04124965) then MG0007 (NCT04650854), or MG0007 directly
  - In MG0004, patients received once-weekly rozanolixizumab 7 mg/kg or 10 mg/kg for ≤52 weeks
  - In MG0007, after an initial 6-week rozanolixizumab 7 mg/kg or 10 mg/kg cycle, subsequent cycles were administered upon symptom worsening at the investigator's discretion
- Final rozanolixizumab efficacy data were pooled across MycarinG, MG0004 (first 6 weeks) and MG0007 for patients with ≥2 symptom-driven rozanolixizumab treatment cycles
- MG-ADL and QMG item-level scores were assessed at baseline and Day 43 across 13 cycles using means weighted by sample size
- Final safety data were pooled across MycarinG and MG0007 for patients with ≥1 treatment cycle; incidence of TEAEs was assessed

Results

- Overall, 129 patients received ≥2 symptom-driven cycles of rozanolixizumab (7 mg/kg or 10 mg/kg)
- Baseline demographics and disease characteristics were indicative of a broad population of patients with gMG (**Table 1**)
- Across Cycles 1–13, a reduction in weighted-mean scores was observed at Day 43 for all MG-ADL and QMG items (**Figure 1**), with a similar pattern of improvement observed within individual cycles
  - The greatest improvements in weighted-mean score between baseline and Day 43 were observed for the following MG-ADL items: eyelid droop, double vision, talking, chewing and brushing hair/teeth
  - For QMG items, the greatest improvements were observed for: ptosis on upward gaze, double vision (lateral gaze) and speech after counting aloud from 1 to 50
- In total, 93.1% (175/188) of patients experienced a TEAE; most were mild or moderate
  - The most common TEAEs were headache (50.0%; n=94/188), diarrhoea (33.5%; n=63/188) and COVID-19 (21.8%; n=41/188)
  - The incidence of TEAEs did not increase with repeated cyclic treatment

Summary and conclusions

This *post hoc* analysis of data pooled across the Phase 3 MycarinG study and its OLEs evaluated the effect of long-term, cyclic rozanolixizumab treatment on MG-ADL and QMG individual item scores

Across Cycles 1–13, rozanolixizumab treatment showed improvements in all MG-ADL and QMG item-level scores, with a similar pattern of improvement observed within individual cycles

Rozanolixizumab treatment led to improvements from baseline across ocular, bulbar, respiratory and limb weakness/gross motor items in MG-specific outcomes, demonstrating consistent benefit across a broad range of signs and symptoms

Figure 1 Weighted-mean scores improved between baseline and Day 43 across all (a) MG-ADL and (b) QMG items, over 13 cycles

Only participants with data at baseline and Day 43 for a cycle were included.
†Combined genders.

Table 1 Baseline demographics and disease characteristics were indicative of a broad population of patients with gMG

		RLZ total (N=129)
Age, years, mean (SD)		**50.9** (16.3)
Sex, female, n (%)		**77** (59.7)
Age at initial gMG diagnosis, years, mean (SD)		**43.1** (17.8)
Duration of disease from diagnosis, years, mean (SD)		**8.1** (8.5)
MGFA Clinical Class, n (%)	II	**52** (40.3)
	III	**72** (55.8)
	IV	**5** (3.9)
Anti-AChR Ab+, n (%)		**117** (90.7)
Anti-MuSK Ab+, n (%)		**12** (9.3)
MG-ADL score, mean (SD)		**8.7** (3.4)
QMG score, mean (SD)		**16.0** (3.8)
Baseline gMG medication, n (%)	CS for systemic use	**80** (62.0)
	Immunosuppressants	**66** (51.2)
	Parasympathomimetics	**113** (87.6)

Abbreviations: Ab+, antibody-positive; AChR, acetylcholine receptor; BL, baseline; CFB, change from baseline; CS, corticosteroid; FcRn, neonatal fragment crystallizable receptor; gMG, generalized myasthenia gravis; IgG4, immunoglobulin G subunit 4; mAb, monoclonal antibody; 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; RLZ, rozanolixizumab; SD, standard deviation; TEAE, treatment-emergent adverse event.

Acknowledgments: *In memoriam of Prof. Vera Bril, whose invaluable contribution to this work is gratefully acknowledged. 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, Slough, UK, 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: Suraj Muley has received grants from argenx, Dianthus, Immunovant, Novartis, Regeneron, Sanofi, Takeda and UCB. Dr Muley has also received royalties or licenses from GBS and UpToDate CIDP, and has served on a speaker bureau for Alexion, Amgen, CSL Behring, Grifols, Johnson & Johnson, Takeda and UCB. Dr Muley has received honoraria for consulting services from Alexion, Amgen, Catalyst, CSL Behring, Grifols, Immunovant, Johnson & Johnson, Takeda, UCB and Vor. Elena Cortés Vicente receives public speaking honoraria and compensation for advisory boards and/or consultation fees from Alexion Pharmaceuticals, argenx, Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine) and UCB. Laura Fionda has received funding for travel and meeting attendance or advisory board participation from Alexion Pharmaceuticals, Amgen, argenx, Dianthus, Johnson & Johnson and UCB. Ali A. Habib has received research support and/or honoraria from Alexion/AstraZeneca Rare Disease, Amgen, Arcellx, 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. 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 panelist 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. Renato Mantegazza has received funding for travel and meeting attendance or advisory board participation from Alexion Pharmaceuticals, argenx, BioMarin, Catalyst, Regeneron Pharmaceuticals, Sanofi 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 organization Medical Education Resources (an educational organization 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. Artur Drużdż and Sabrina Sacconi have nothing to disclose. Kimiaki Utsugisawa has served as a paid Consultant for argenx, Chugai Pharmaceutical, HanAll Biopharma, Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine), Merck, Mitsubishi Tanabe Pharma, UCB and Viela Bio (now Amgen); he has received speaker honoraria from Alexion Pharmaceuticals, argenx, the Japan Blood Products Organization and UCB. 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, ImmunAbs, 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. Jos Bloemers, Paul Mahoney and Thaïs Tarancón are employees and shareholders of UCB. Vera Bril was a Consultant for Akcea, 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 received research support from Akcea, Alexion Pharmaceuticals, argenx, CSL, Grifols, Immunovant, Ionis, Momenta (now Johnson & Johnson), Octapharma, Takeda Pharmaceuticals, UCB and Viela Bio (now Amgen).

References: 1. Gilhus NE, et al. Nat Rev Dis Primers. 2019;5(1):30. 2. de Meel RHP, et al. Lancet Neurol. 2018;17(3):204–205. 3. Bril V, et al. Eur J Neurol. 2024;31(1):e16098. 4. RYSTIGGO® US PI. https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf. Accessed August 2026. 5. Smith B, et al. MAbs. 2018;10(7):1111–1130. 6. Bril V, et al. Lancet Neurol. 2023;22(5):383–394.

Please use this QR code to download a PDF of the poster.

These data were previously presented at ICNMD 2026, Florence, Italy; July 7–11, 2026