Quality of life in myasthenia gravis: *Post hoc* pooled analysis of Phase 3 rozanolixizumab studies

Ali A. Habib[1], Zabeen K. Mahuwala[2], Renato Mantegazza[3], Robert M. Pascuzzi[4], Sabrina Sacconi[5], John Vissing[6], Jana Zschüntzsch[7] Jos Bloemers[8], Paul Mahoney[9], Thaïs Tarancón[10], Vera Bril[11]*

[1]MDA ALS & Neuromuscular Center, Department of Neurology, University of California, Irvine, Orange, CA, USA; [2]Department of Neuromuscular Medicine, Epilepsy and Clinical Neurophysiology, University of Kentucky, Lexington, KY, USA; [3]Emeritus and Past Director, Department of Neuroimmunology and Neuromuscular Diseases, Fondazione IRCCS, Istituto Nazionale Neurologico Carlo Besta, Milan, Italy; [4]Neurology Department, Indiana University School of Medicine, Indiana University Health, Indianapolis, IN, USA; [5]Université Côte d'Azur, Peripheral Nervous System & Muscle Department, Pasteur 2 Hospital, Centre Hospitalier Universitaire de Nice, Nice, France; [6]Copenhagen Neuromuscular Center, Department of Neurology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; [7]Department of Neurology, University Medical Center Göttingen, Göttingen, Germany; [8]UCB, Breda, Netherlands; [9]UCB, Slough, UK; [10]UCB, Madrid, Spain; [11]Ellen and Martin Prosserman Centre for Neuromuscular Diseases, Toronto General Hospital, University of Toronto, Toronto, Ontario, Canada

AANEM & MGFA Scientific Session 2026, Orlando, FL, USA; September 29–October 2, 2026

Introduction

- gMG is a chronic, autoimmune, neuromuscular disease that can significantly affect patients' HRQoL[1]
- The MG-QoL15r is a PRO measure that investigates the physical, social and emotional impact of MG on HRQoL[2]
- 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[3,4]
- In the randomized, double-blind, Phase 3 MycarinG study (NCT03971422), one 6-week cycle of rozanolixizumab improved MG-QoL15r total scores compared with placebo in patients with gMG (LS mean difference from placebo in CFB to Day 43: −2.2 [p=0.018] and −3.7 [p<0.001] with rozanolixizumab 7 mg/kg and 10 mg/kg, respectively)[5,6]
- **This *post hoc* analysis evaluated the effect of long-term, cyclic rozanolixizumab treatment on patients' HRQoL using MG-QoL15r item-level scores**

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
  - MG0007 comprised an initial 6-week rozanolixizumab 7 mg/kg or 10 mg/kg cycle, with further cycles administered upon symptom worsening at the investigator's discretion
- Final efficacy data were pooled across MycarinG, MG0004 (first 6 weeks) and MG0007 for patients with ≥2 symptom-driven rozanolixizumab treatment cycles
  - CFB to Day 43 in MG-QoL15r item-level scores across Cycles 1–13 was assessed *post hoc* 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
- Across Cycles 1–13 (N=890), weighted-mean (SD) MG-QoL15r total score decreased from 15.0 (7.2) at baseline to 10.4 (7.4) at Day 43
- Similarly, weighted-mean scores improved between baseline and the end of each 6-week rozanolixizumab cycle (Day 43) for all MG-QoL15r items across Cycles 1–13 (**Figure 1**)
  - The greatest improvements in weighted-mean score between baseline and Day 43 were observed for the items "trouble eating", "difficulty speaking", "trouble using my eyes" and "bothered by limitations in performing work"
- Across Cycles 1–13 (weighted average), the proportion of patients who improved to having no symptom impacts at Day 43 was greatest for the MG-QoL15r items "trouble eating" and "difficulty speaking" (**Figure 2**)
- In total, 93.1% (175/188) of patients experienced a TEAE; most were mild or moderate
  - The incidence of TEAEs did not increase with repeated cyclic treatment
  - The three most common TEAEs were headache (50.0% [94/188]), diarrhea (33.5% [63/188]) and COVID-19 (21.8% [41/188])

Summary and conclusions

In this *post hoc* analysis of MycarinG and its OLE studies, the effect of long-term, cyclic rozanolixizumab treatment on patients' HRQoL was evaluated using MG-QoL15r item-level scores

Long-term rozanolixizumab treatment across 13 cycles led to improvements in all MG-QoL15r item-level scores over multiple cycles

This *post hoc* analysis demonstrated that long-term use of rozanolixizumab had consistent efficacy across the range of impacts on HRQoL caused by MG symptoms

Figure 1 Across all MG-QoL15r items, weighted-mean scores improved between baseline and Day 43 over 13 cycles

Efficacy pool, defined as patients with ≥2 symptom-driven cycles. N=890. †N=889.

Figure 2 Across Cycles 1–13, each MG-QoL15r item-level score was improved in up to 38.5% of patients

Efficacy pool. Percentages may not add to 100% due to rounding.

Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; CFB, change from baseline; FcRn, neonatal fragment crystallizable receptor; gMG, generalized myasthenia gravis; HRQoL, health-related quality of life; IgG4, immunoglobulin G4; LS, least squares; mAb, monoclonal antibody; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MG-QoL15r, Myasthenia Gravis Quality of Life 15-item revised; MuSK, muscle-specific tyrosine kinase; OLE, open-label extension; PRO, patient-reported outcome; QMG, Quantitative Myasthenia Gravis; 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 Bea Perks, PhD, of Ogilvy Health, London, UK, and Beatrix Poulton, BSc (Hons), 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: 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 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. 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 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. Sabrina Sacconi has nothing to disclose. 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. Jana Zschüntzsch has been awarded research grants from the German Innovationfond, German Society for Muscle Disease (DGM), and the Innovative Medicines Initiative 2 Joint Undertaking (IMI JU) of the European Commission (grant number: 101034427-2). She has received speaker honoraria or travel grants from Alexion, argenx, Kedrion, Roche and Sanofi. She serves on scientific or educational advisory boards for Alexion, Amicus, argenx, iThera, Kedrion, Sanofi, and UCB. She has received research support from argenx and UCB. She is a member of the European Reference Network for Rare Neuromuscular Diseases (ERN EURO-NMD) and a member of the medical advisory boards of the DGM and the German Myasthenia Gravis Society. 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. Jackson K, et al. Neurol Ther. 2023;12(1):107–128. 2. Burns TM, et al. Muscle Nerve. 2016;54(6):1015–1022. 3. RYSTIGGO® US PI. https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf. Accessed August 2026. 4. Smith B, et al. mAbs. 2018;10(7):1111–1130. 5. Bril V, et al. Lancet Neurol. 2023;22(5):383–394. 6. Sacconi S, et al. Quality of life in patients with generalised myasthenia gravis receiving rozanolixizumab: *Post hoc* analysis of MycarinG [poster]. EAN 2025. Poster EPO-307.

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