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

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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 humanised 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 randomised, 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 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
- Following MycarinG, patients could enrol 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]), diarrhoea (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

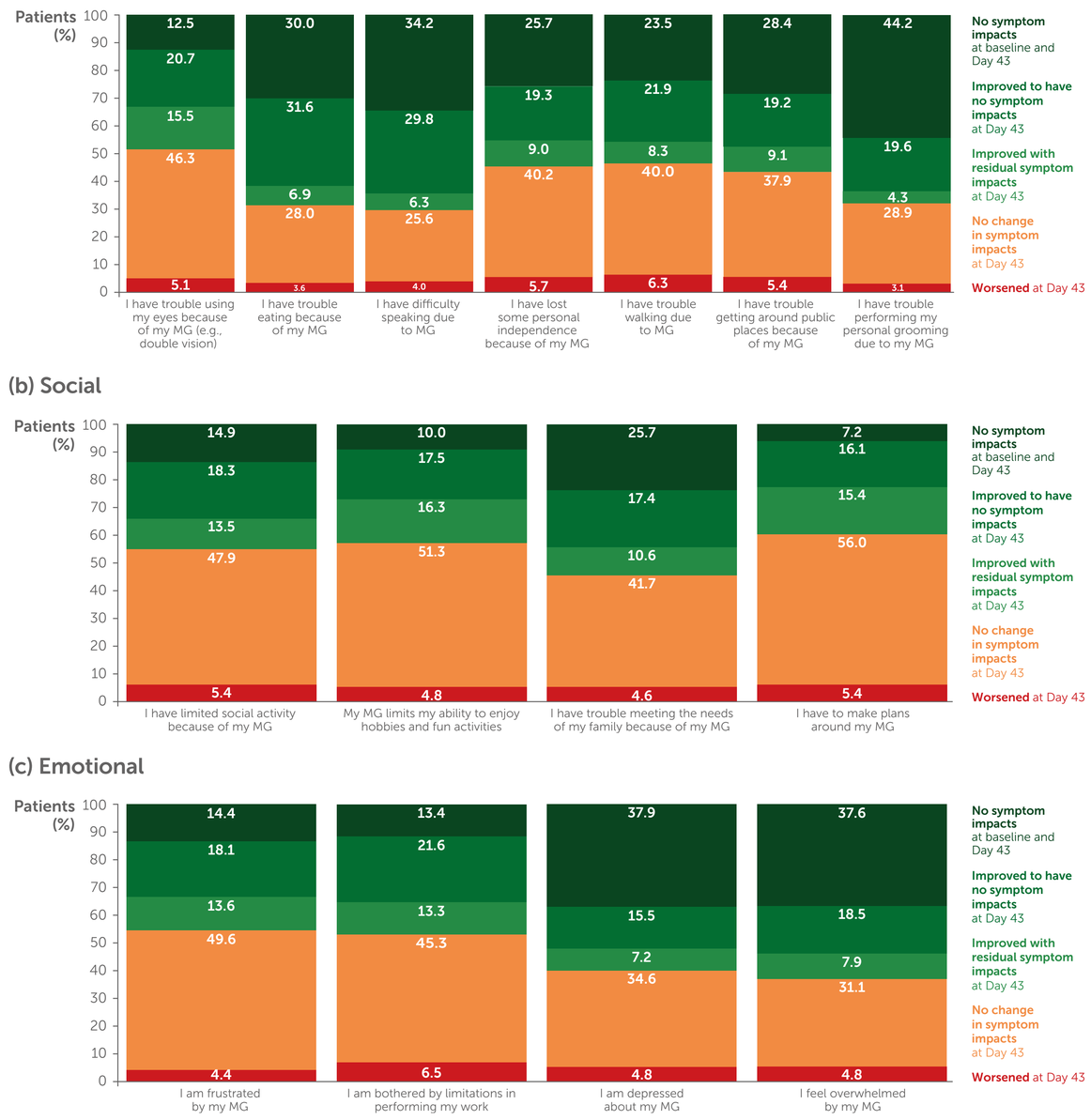
Long-term rozanolixizumab treatment across 13 cycles led to improvements in all MG-QoL15r item-level scores over multiple cycles

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 100.0% due to rounding.

Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; CFB, change from baseline; FcRn, neonatal fragment crystallisable receptor; gMG, generalised 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.

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