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

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Introduction

- gMG is a chronic, autoimmune, neuromuscular disease that is characterised by fluctuating muscle weakness, with treatment responses varying across different muscle groups[1–3]
- 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[4,5]
- In the randomised, 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 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
  - 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

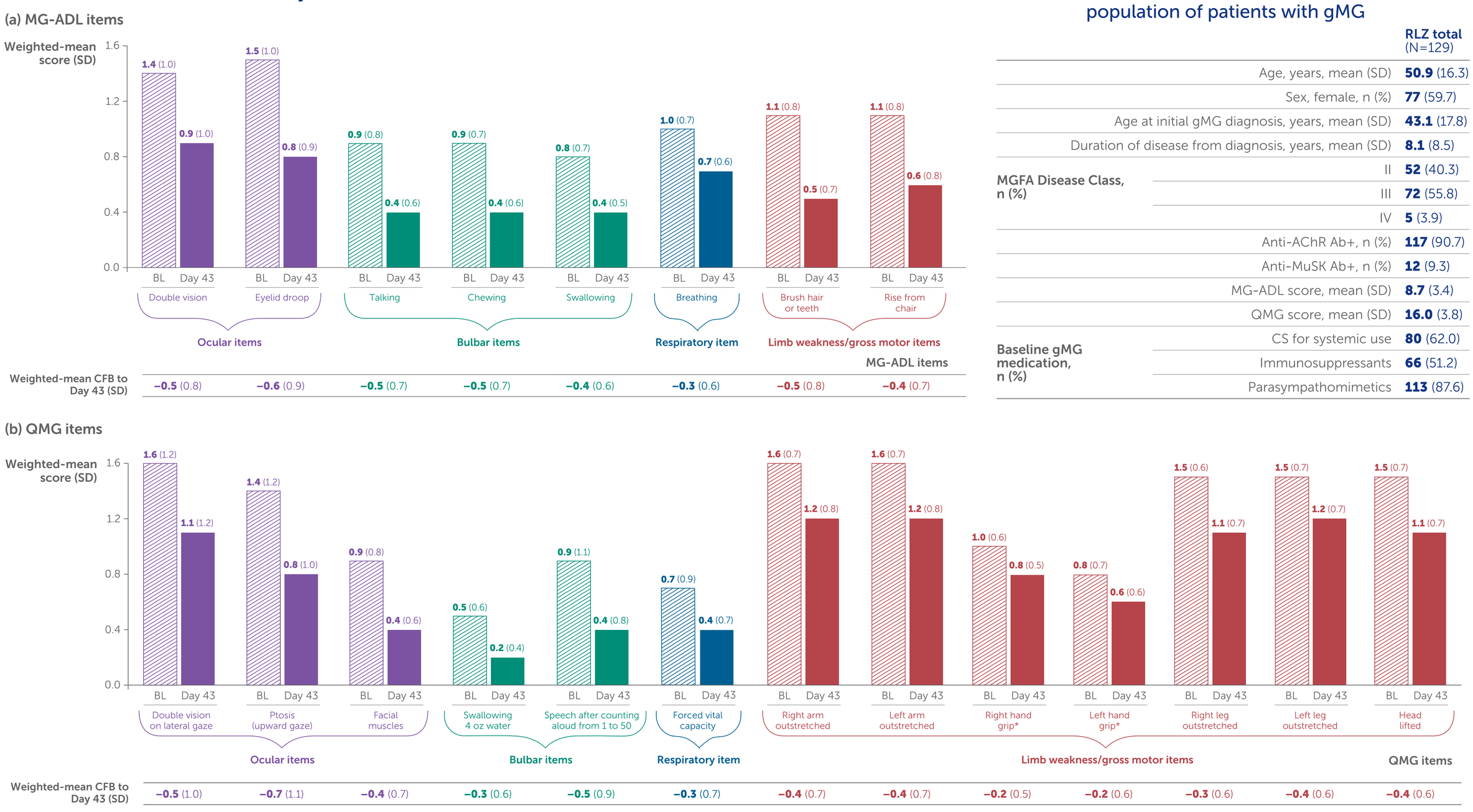

Table 1 Baseline demographics and disease characteristics were indicative of a broad population of patients with gMG

		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 Disease 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)

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

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

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