Effect of rozanolixizumab on ocular symptoms in generalised myasthenia gravis: Analysis of Phase 3 studies

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Introduction

- Patients with gMG may experience disabling ocular symptoms, such as diplopia and ptosis, due to ocular muscle weakness and fatigability[1–3]
  - Such ocular symptoms impede daily activities and significantly reduce QoL[4]
- 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]
- In the Phase 3 MycarinG study (NCT03971422), one 6-week cycle of rozanolixizumab demonstrated greater improvements in ocular item scores across MG-specific outcomes than placebo in patients with gMG[5]
- **This *post hoc* analysis investigated the effect of repeated rozanolixizumab treatment cycles on ocular symptoms in patients with gMG**

Methods

- In MycarinG, patients 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 were enrolled
- Following MycarinG, patients could enrol in OLE studies MG0004 (NCT04124965) and MG0007 (NCT04650854), or MG0007 directly
  - MG0004: once-weekly rozanolixizumab 7 mg/kg or 10 mg/kg for ≤52 weeks
  - MG0007: 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 cycles
- Mean item scores (weighted by sample size, per cycle) were evaluated at baseline and Day 43 across Cycles 1–13 for ocular items within the MG-ADL, QMG, MG Symptoms PRO and MG-QoL15r scales

Results

- Overall, 129 patients received ≥2 symptom-driven cycles
- Baseline demographics and disease characteristics are shown in **Table 1**
- Across 13 cycles, weighted mean ocular item-level scores improved between baseline and Day 43 for MG-ADL, QMG, MG Symptoms PRO and MG-QoL15r (**Figure 1**)
- Across Cycles 1–13 (weighted mean), the percentages of patients who improved to have no symptoms in each ocular item-level score across all four measures ranged from 20.7% (MG-QoL15r; "I have trouble using my eyes") to 31.1% (MG-ADL; eyelid droop) (**Figure 2**)
- In total, 93.1% (175/188) of patients with ≥1 treatment cycle across MycarinG and MG0007 experienced a TEAE; most were mild or moderate

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)
MG-ADL ocular subdomain score, mean (SD)		**2.8** (1.7)
QMG score, mean (SD)		**16.0** (3.8)
QMG ocular subdomain score, mean (SD)		**4.0** (1.9)
Baseline gMG medication, n (%)	CS for systemic use	**80** (62.0)
	Immunosuppressants	**66** (51.2)
	Parasympathomimetics	**113** (87.6)

Summary and conclusions

This *post hoc* analysis of pooled data from the Phase 3 MycarinG study and its OLEs evaluated the effect of long-term, cyclic rozanolixizumab treatment on the ocular signs and symptoms experienced by patients with gMG

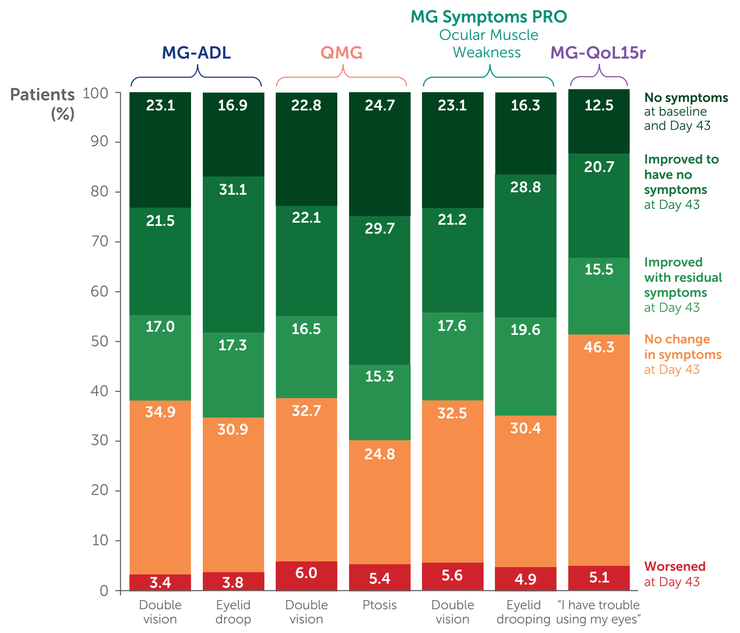
Long-term rozanolixizumab treatment cycles led to improvements across ocular items in MG-specific outcome measures, suggesting a benefit for patients with gMG experiencing ocular signs and symptoms

Following these results, rozanolixizumab is being investigated in the MyVision study (NCT07463521) in patients with ocular MG

Figure 1 Across 13 cycles, weighted mean ocular item-level scores improved between baseline and Day 43 for (a) MG-ADL, (b) QMG, (c) MG Symptoms PRO and (d) MG-QoL15r measures

Individual item scores for MG Symptoms PRO range from 0–3; MG Symptoms PRO subdomain scores are transformed from the raw scores to a range of 0–100.

Figure 2 Most patients' ocular item-level scores improved across Cycles 1–13



Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; CS, corticosteroid; FcRn, neonatal fragment crystallisable receptor; (g)MG, (generalised) myasthenia gravis; IgG4, immunoglobulin G4; mAb, monoclonal antibody; 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; QoL, quality of life; RLZ, rozanolixizumab; SD, standard deviation; TEAE, treatment-emergent adverse event.

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