Efficacy of long-term rozanolixizumab treatment cycles in patients with generalised myasthenia gravis: A subgroup analysis of Phase 3 studies

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Introduction

- 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[1,2]
- In the Phase 3 MycarinG (NCT03971422) study, one 6-week cycle of rozanolixizumab (7 mg/kg or 10 mg/kg) improved MG-specific outcomes versus placebo[3]
- **This analysis evaluated the long-term efficacy of repeated rozanolixizumab treatment cycles across MycarinG and its OLE studies in subgroups of patients with gMG**

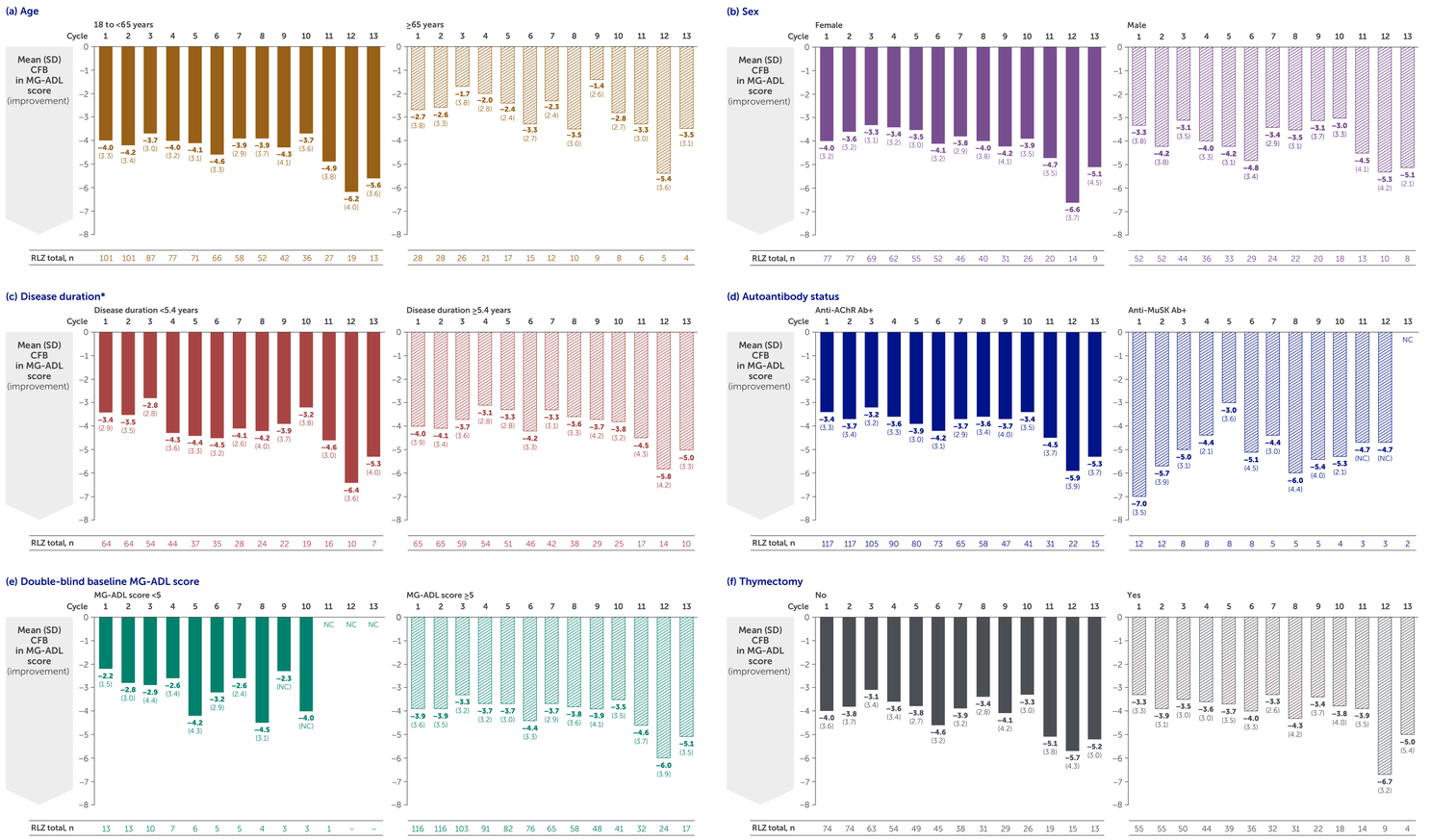
Methods

- 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 cycle of rozanolixizumab 7 mg/kg or 10 mg/kg, 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 CFB in MG-ADL score to Day 43 in Cycles 1–13 was assessed in the following prespecified subgroups:
  - Age (18 to <65 years/≥65 years)
  - Sex (female/male)
  - Disease duration (<median/≥median)
  - Autoantibody status (anti-AChR Ab+/anti-MuSK Ab+)
  - Double-blind baseline MG-ADL score (<5/≥5)
  - Thymectomy (no/yes)
- 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 (**Table 1**)
  - Between respective subgroups, baseline demographics and disease characteristics were generally similar (data not shown)
- Mean (SD) CFB in MG-ADL score at Day 43 across Cycles 1–13 for the overall population ranged from −3.2 (3.3) in Cycle 3 (n=113) to −6.0 (3.9) in Cycle 12 (n=24)
- Improvements from baseline in MG-ADL scores at Day 43 were generally consistent between the overall study population and prespecified subgroups across repeated cycles of rozanolixizumab (**Figure 1**)
- TEAEs occurred in 93.1% (n/N=175/188) of patients; most were mild or moderate
  - In general, the incidence of TEAEs was similar across subgroups

Figure 1 Improvements from baseline in MG-ADL scores at Day 43 were generally consistent within each prespecified subgroup



Efficacy pool. *Disease duration categorised as < or ≥ the median (5.4 years).

Summary and conclusions

This pooled analysis of data from the Phase 3 MycarinG study and its OLEs evaluated the long-term efficacy and safety of repeated rozanolixizumab treatment cycles across prespecified subgroups

Improvement from baseline in MG-ADL to Day 43 was maintained over repeated cycles of treatment in the overall population and in prespecified subgroup populations of age, sex, disease duration, autoantibody status, double-blind baseline MG-ADL score and thymectomy status

Rozanolixizumab efficacy was maintained across multiple treatment cycles in a broad population of patients with gMG

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 (%)	Corticosteroids for systemic use	**80** (62.0)
	Immunosuppressants	**66** (51.2)
	Parasympathomimetics	**113** (87.6)

Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; CFB, change from baseline; FcRn, neonatal fragment crystallisable receptor; gMG, generalised myasthenia gravis; IgG4, immunoglobulin G4; mAb, monoclonal antibody; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MuSK, muscle-specific tyrosine kinase; NC, not calculated; OLE, open-label extension; QMG, Quantitative Myasthenia Gravis; RLZ, rozanolixizumab; SD, standard deviation; TEAE, treatment-emergent adverse event.

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