

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

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Introduction

- 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.^{1,2}
- In the Phase 3 MycarinG study (NCT03971422), one 6-week cycle of rozanolixizumab (7 mg/kg or 10 mg/kg) improved MG-specific outcomes versus placebo³
- 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 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 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
- MG-ADL scores at baseline and Day 43, and MG-ADL response rate (≥2.0-point improvement from baseline without rescue therapy) at Day 43, were assessed over Cycles 1–13 using means weighted by sample size

- Subgroups were prespecified according to baseline demographics and disease characteristics:
 - Age (18 to <65 years/≥65 years)
 - Sex (female/male)
 - Disease duration from diagnosis (<median/≥median)
 - Autoantibody status (anti-AChR Ab+/anti-MuSK Ab+)
 - 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
 - Between respective subgroups, baseline demographics and disease characteristics were generally similar (data not shown)
- Across Cycles 1–13, weighted-mean (SD) MG-ADL total score for the overall population (N=939) decreased from 8.5 (3.5) at baseline to 4.7 (3.7) at Day 43
 - Weighted-mean improvements in MG-ADL score from baseline to Day 43 over Cycles 1–13 were generally consistent between the overall study population and prespecified subgroups (**Figure 1**)
- The weighted-mean MG-ADL responder rate at Day 43 over Cycles 1–13 was 74.0% for the overall population (n/N=695/939)
 - Weighted-mean responder rates at Day 43 over Cycles 1–13 were generally consistent between the overall study population and prespecified subgroups (**Figure 2**)
- 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 (data not shown)

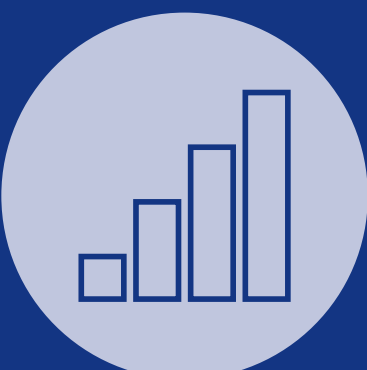
Summary and conclusions



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, baseline MG-ADL score and thymectomy status

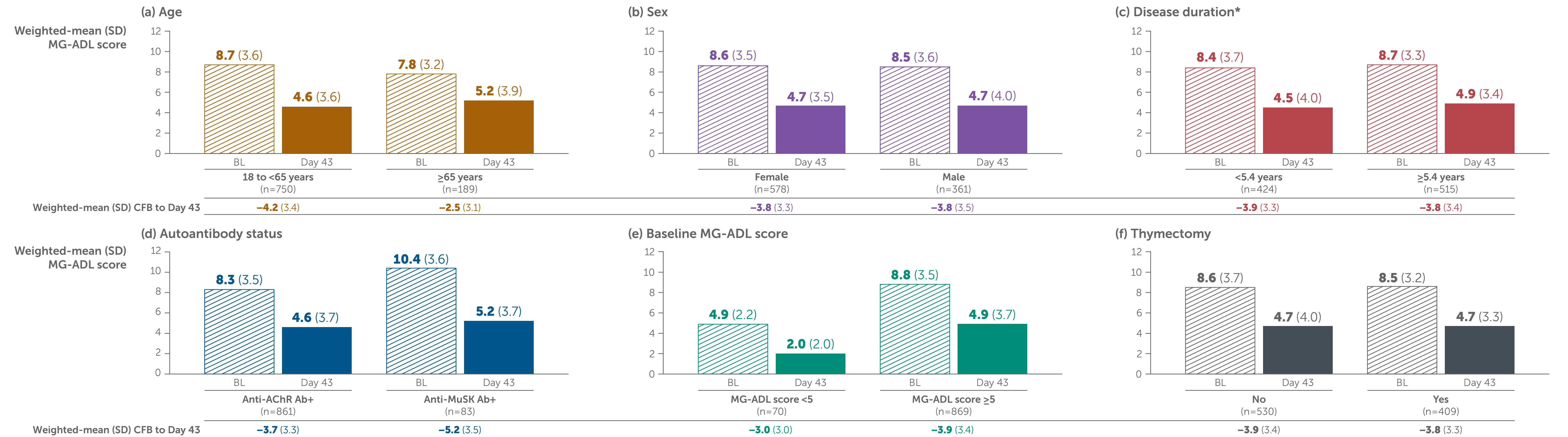


Weighted-mean MG-ADL response rates were high and generally consistent between the overall population and the prespecified subgroup populations



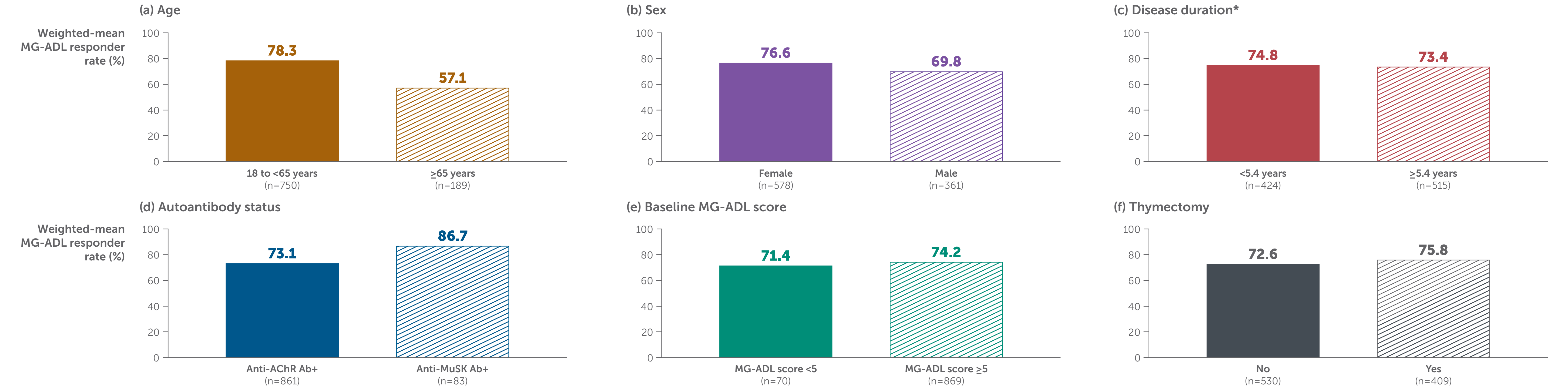
Rozanolixizumab efficacy was maintained across repeated treatment cycles in a broad population of patients with gMG

Figure 1 Weighted-mean MG-ADL scores improved between baseline and Day 43 across Cycles 1–13 and were generally consistent within and across each prespecified subgroup



Efficacy pool; patients with ≥2 symptom-driven rozanolixizumab cycles. *Disease duration from diagnosis categorized as < or ≥ the median (5.4 years).

Figure 2 Weighted-mean MG-ADL responder rates at Day 43 over Cycles 1–13 were high and generally consistent within and across each prespecified subgroup



Efficacy pool; patients with ≥2 symptom-driven rozanolixizumab cycles. MG-ADL response is defined as a ≥2.0-point improvement in MG-ADL score from baseline without rescue therapy. *Disease duration from diagnosis categorized as < or ≥ the median (5.4 years).

Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; BL, baseline; CFB, change from baseline; FcRn, neonatal fragment crystallizable receptor; gMG, generalized myasthenia gravis; IgG4, immunoglobulin G subclass 4; 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; OLE, open-label extension; QMG, Quantitative Myasthenia Gravis; SD, standard deviation; TEAE, treatment-emergent adverse event.
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