

Efficacy of Nipocalimab in Open-Label Extension in Patients Transitioned from Placebo: Results from Vivacity-MG3 Trial



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Key Takeaways

- Placebo+SOC arm patients who transitioned to nipocalimab+SOC in OLE exhibited early and clinically meaningful improvements that were sustained up to OLE Week 24.

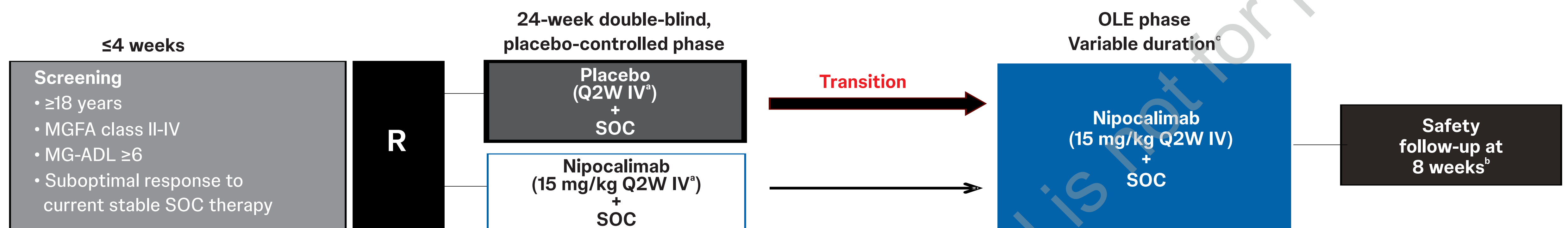
Introduction

- Generalized myasthenia gravis (gMG) is a rare chronic condition characterized by muscle weakness caused by autoantibody-mediated disruption of neurotransmission that severely affects the daily functioning and health-related quality of life.^{1,2}
- Vivacity-MG3 study:** A 24-week, phase 3, randomized, double-blind (DB) study evaluated efficacy and safety of nipocalimab, a monoclonal antibody that blocks neonatal fragment crystallizable receptor (FcRn) to reduce levels of circulating IgG antibodies, added to standard-of-care (SOC) versus (vs) placebo+SOC in patients with gMG.³
 - The findings from this study supported the recent United States Food and Drug Administration (U.S. FDA) approval of nipocalimab.⁴ The European Medicines Agency Committee for Medicinal Products for Human Use recently (September 2025) recommended authorizing the marketing of nipocalimab added to standard-care therapy for treatment of gMG in adults and adolescents (aged ≥12 years of age) who are anti-AChR or anti-MuSK antibody positive.⁵
- Patients on placebo+SOC in the DB phase of Vivacity-MG3 could transition to receive nipocalimab+SOC in the ongoing open-label extension (OLE) phase.

Objective

To assess the efficacy of nipocalimab+SOC in OLE phase in patients transitioned from placebo+SOC arm of DB phase of the Vivacity-MG3 study.

Study Design



*All patients received the loading dose of placebo or nipocalimab 30 mg/kg at Week 0 and then started placebo or nipocalimab 15 mg/kg Q2W IV from week 2 to week 24; *Participants who withdraw or discontinue after receiving any amount of study intervention are required to complete a safety follow-up visit 8 wks after their last dose; *In the EU, the OLE phase will be up to 240 wks. DB=Double-blind; IV=Intravenous; MG-ADL=Myasthenia Gravis-Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; OLE=Open-label extension; Q2W=Every 2 weeks; R=Randomized 1:1; SOC=Standard-of-care.

Assessments based on MG-ADL and QMG

Assessments

Improvement in MG-ADL and QMG total score from OLE baseline

- Mean changes in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores.
 - Within-group mean changes were examined using paired t-test.
- Proportion of patients achieving meaningful clinical improvements (MCI) (≥2-point improvement^{6,7} in MG-ADL total score [MG-ADL-2]).
- Proportion of patients achieving minimal symptom expression (MSE) (MG-ADL score of 0 or 1).
- Proportion of patients with sustained MCI and MSE for ≥8 weeks.
- Percentage of time spent in MCI and MSE.

Results

Population

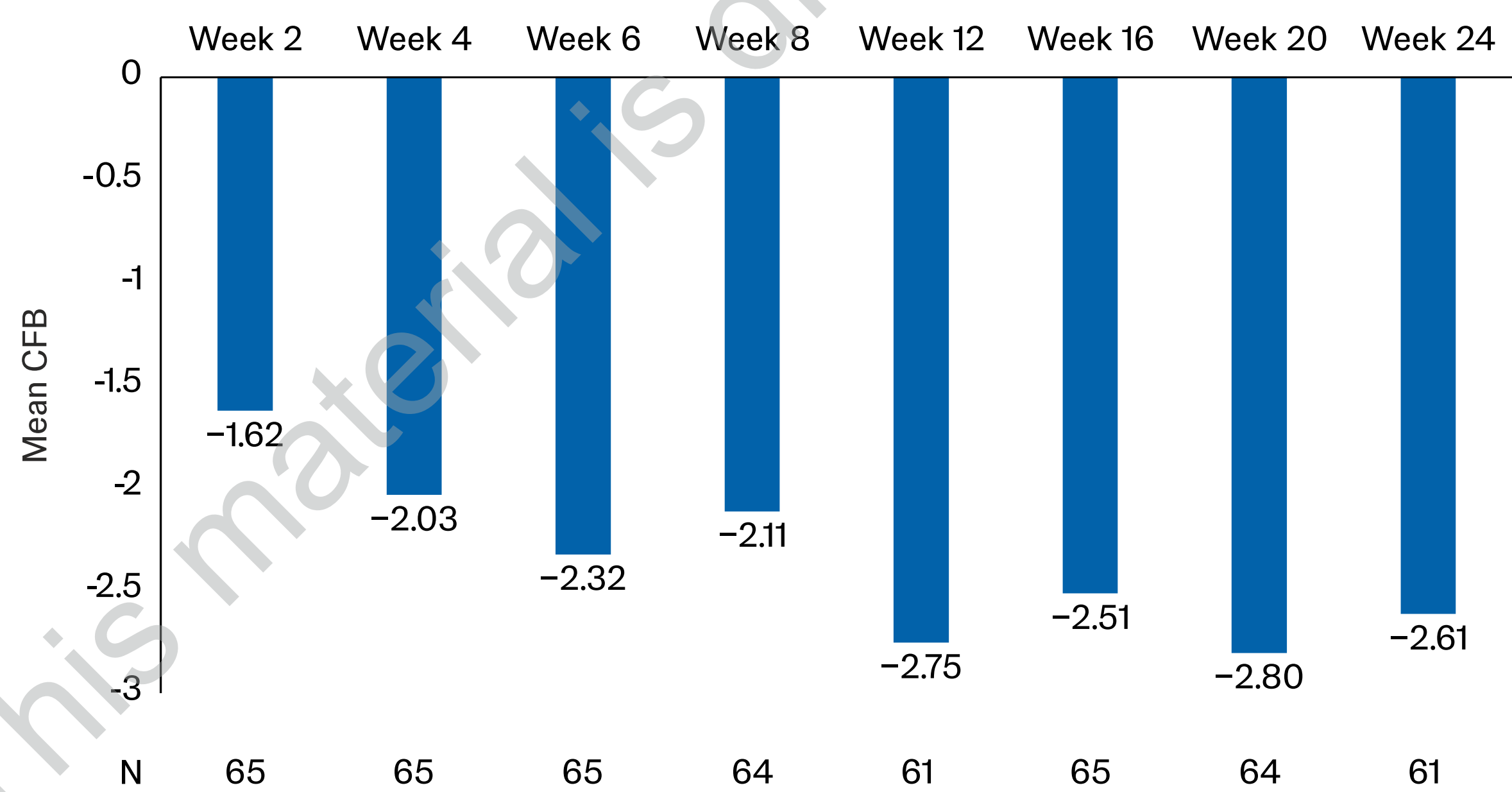
Analysis population and exposure

- Overall, 76 patients from placebo+SOC arm completed DB phase and 66 of them transitioned to nipocalimab+SOC in OLE phase. OLE efficacy analysis set included 66 patients
- Data were collected up to OLE Week 24 (cutoff: 23-August-2024)
- The mean (standard deviation [SD]) duration of nipocalimab exposure was: 68.6 (25.69) weeks, n=66
 - 63 (95.5%) patients had nipocalimab exposure for ≥6 months
 - 46 (69.7%) patients had nipocalimab exposure for ≥12 months

Improvements in MG-ADL score

- Mean (SD) MG-ADL score at OLE baseline^a: 5.94 (2.95)
- Improvements in MG-ADL score were observed as early as OLE Week 2 (Figure 1)
- Mean (SD) change from baseline (CFB) in MG-ADL score:
 - At Week 2: -1.62 (2.19), p<0.001
 - At Week 24: -2.61 (2.62), p<0.001

Figure 1: Mean improvements in MG-ADL score

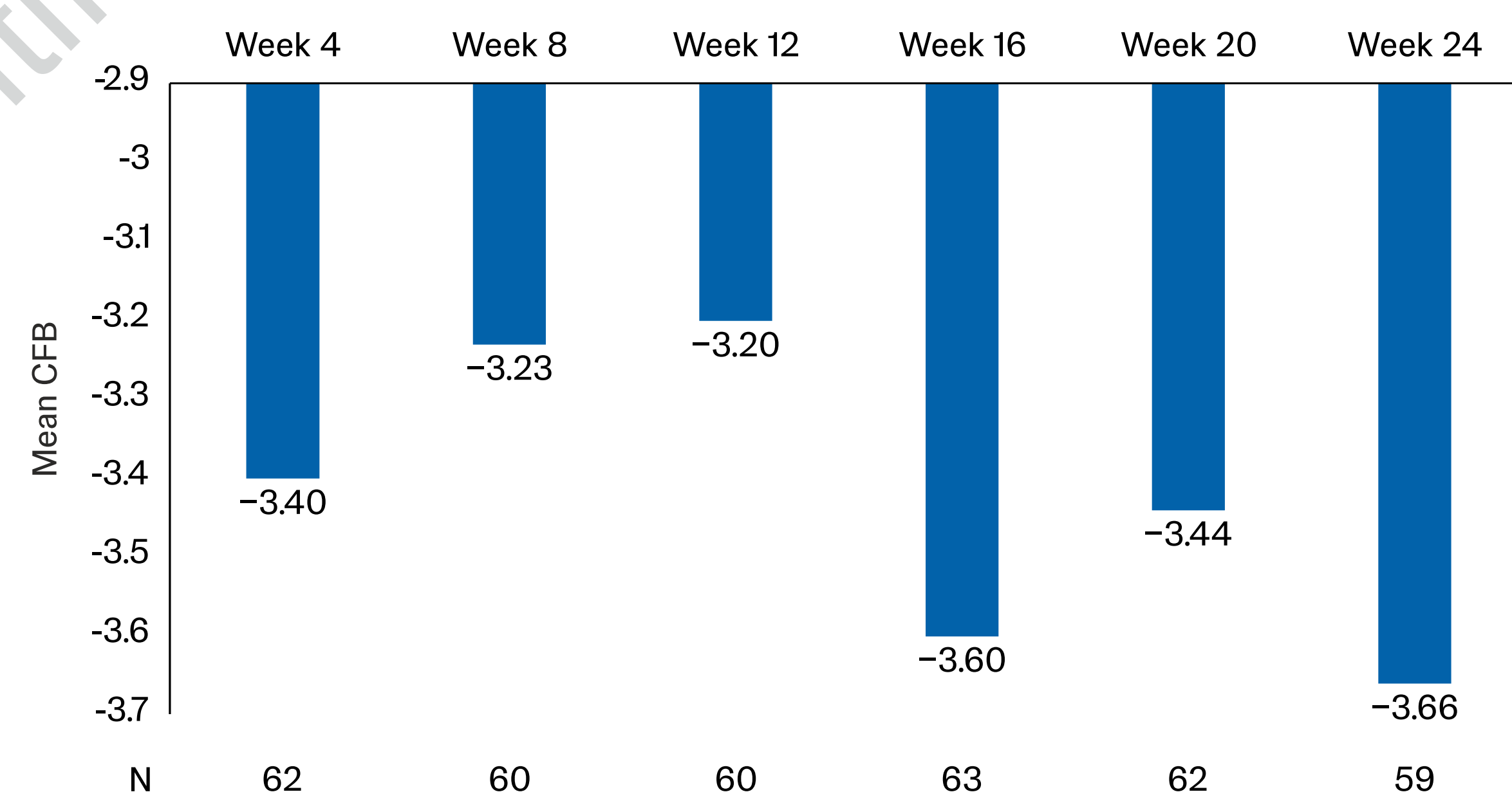


Note: Negative change in score indicates improvement. P-value for comparison of MG-ADL total score change from baseline significantly different from zero using a one-sample t-test. *Baseline value is the last value in the double-blind phase. CFB=Change from baseline; MG-ADL=Myasthenia Gravis-Activities of Daily Living.

Improvements in QMG score

- Mean (SD) QMG score at OLE baseline^a: 13.42 (5.65)
- Improvements in QMG score were observed as early as OLE Week 4 (Figure 2)
- Mean (SD) CFB in QMG score:
 - At Week 4: -3.40 (3.85), p<0.001
 - At Week 24: -3.66 (4.50), p<0.001

Figure 2: Mean improvements in QMG score

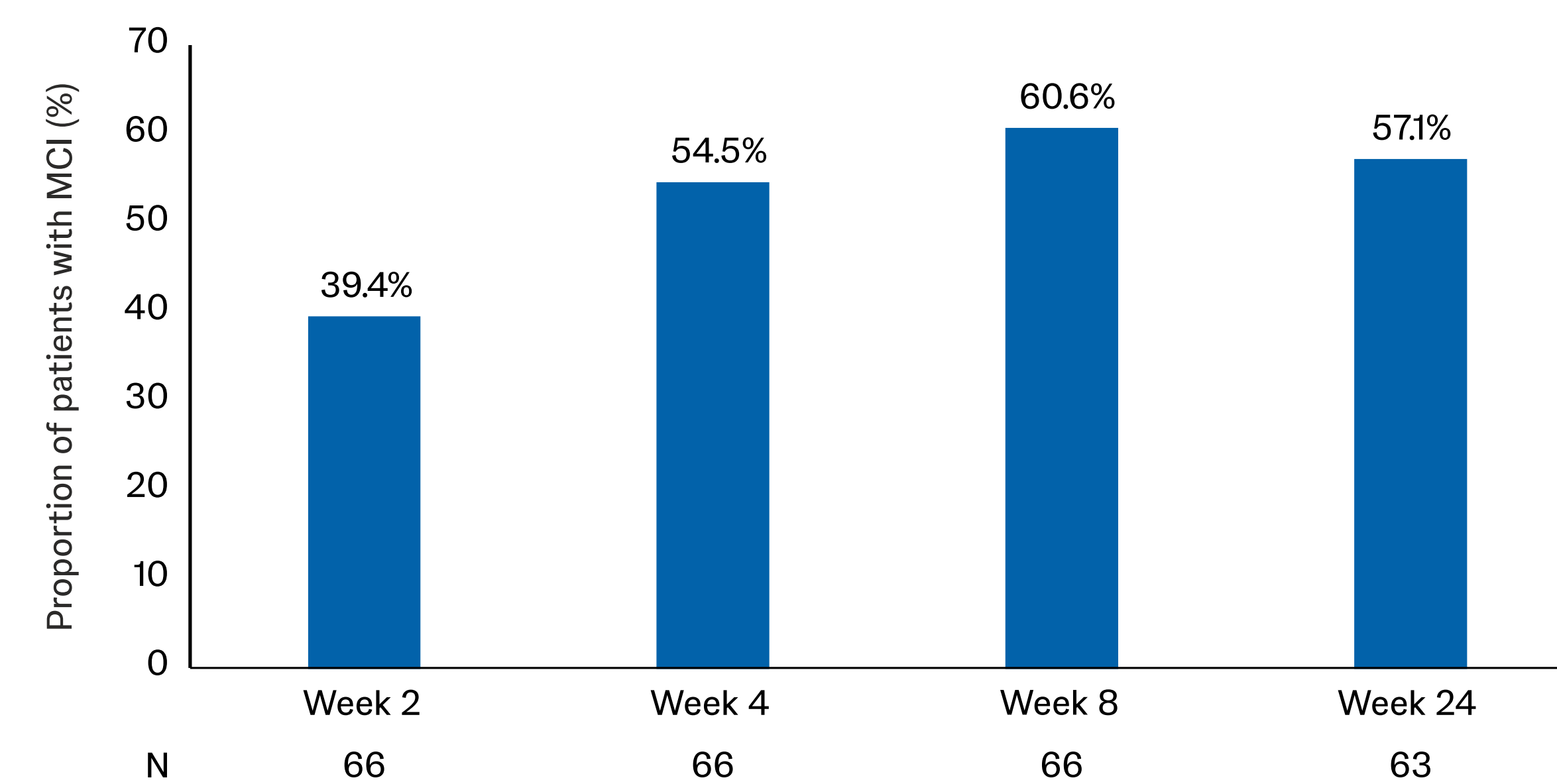


Note: Negative change in score indicates improvement. P-value for comparison of QMG total score change from baseline significantly different from zero using a one-sample t-test. *Baseline value is the last value in the double-blind phase. CFB=Change from baseline; QMG=Quantitative Myasthenia Gravis.

Proportion of patients achieving and sustaining MCI

- At OLE Week 24, 57.1% of patients achieved MCI in MG-ADL (MG-ADL-2) (Figure 3)
 - Earliest week MCI (mean [SD]) occurred at 7.3 (13.50) week
 - Sustained MCI for ≥8 weeks: 46 (69.7%) of patients
- Percentage of time with MCI
 - Mean (SD) percentage of time^b with MCI up to OLE Week 24: 49.5 (39.20)%
 - ≥50% study time with MCI, n (%): 37 (56.1%) patients
 - ≥75% study time with MCI, n (%): 28 (42.4%) patients

Figure 3: Proportion of patients achieving MCI^a in MG-ADL score through OLE Week 24

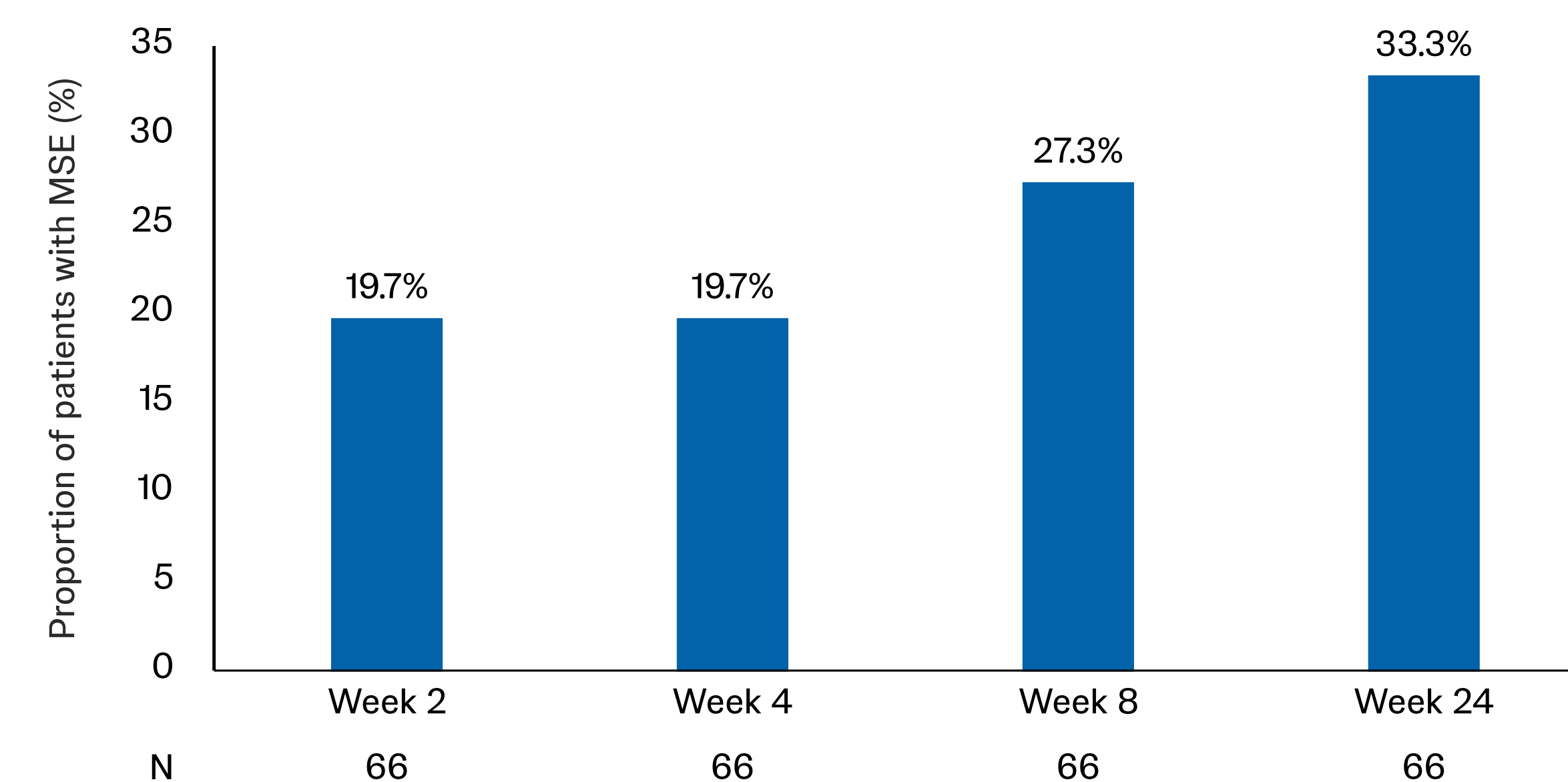


Note: Any patient without a score at a given week were considered as not meeting the MCI conditions. *Minimal clinical improvement is defined as MG-ADL total score improvement of at least 2-points from OLE baseline. *Percentage of time with improvement calculated as cumulative days of improvement divided by number of days in OLE up to Week 24. MCI=Meaningful clinical improvement; MG-ADL=Myasthenia Gravis-Activities of Daily Living; OLE=Open-label extension.

Proportion of patients achieving and sustaining MSE

- At OLE Week 24, 33.3% of patients achieved MSE in MG-ADL (MG-ADL=0 or 1) (Figure 4)
 - Earliest week MSE (mean [SD]) occurred at 12.1 (18.34) week
 - Sustained MSE for ≥8 weeks: 25 (37.9%) of patients
- Percentage of time with MSE
 - Mean (SD) percentage of time^b with MSE up to OLE Week 24: 23.4 (35.30)%
 - ≥50% study time with MSE, n (%): 16 (24.2%) patients

Figure 4: Proportion of patients achieving MSE^a in MG-ADL score through OLE Week 24



Note: Any patient without a score at a given week were considered as not meeting the MSE conditions. *MSE is defined as MG-ADL score of 0 or 1. *Percentage of time with improvement calculated as cumulative days of MSE divided by number of days in OLE up to Week 24. MG-ADL=Myasthenia Gravis-Activities of Daily Living; MSE=Minimal symptom expression; OLE=Open-label extension.