

Assessment of Sustained Health-Related Quality of Life in Phase 3 Vivacity-MG3 Trial of Nipocalimab Versus Placebo in Generalized Myasthenia Gravis

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Key Takeaways

- ✓ Patients with gMG treated with nipocalimab+SOC achieved significantly greater improvement in EQ-5D-VAS and numerically greater improvements in MGQoL-15r over time.
- ✓ A greater proportion of patients treated with nipocalimab+SOC vs placebo+SOC achieved meaningful improvements in EQ-5D-VAS.
- ✓ Patients treated with nipocalimab+SOC achieved meaningful improvements in HRQoL as early as 4 weeks after treatment initiation.
- ✓ Nipocalimab+SOC-treated patients were significantly more likely to achieve and sustain these improvements over 24 weeks as compared with placebo+SOC.

Introduction

- Generalized myasthenia gravis (gMG), a rare autoimmune disorder of the neuromuscular junction, is characterized by fluctuating muscle weakness and fatigability.¹
- Patients with gMG experience various symptoms including chronic fatigue which has a negative impact on activities of daily living and health-related quality of life (HRQoL). Patients with gMG have substantially reduced HRQoL.^{2,3}
- Nipocalimab is the first approved neonatal Fc receptor (FcRn) blocker for the treatment of anti-acetylcholine receptor (anti-AChR) or anti-muscle-specific tyrosine kinase (anti-MuSK) antibody positive gMG in adult and adolescent (≥12 years of age) patients.^{4,5}
- In the Vivacity-MG3 (NCT04951622) study, nipocalimab added to standard-of-care (SOC) demonstrated rapid and sustained disease control versus placebo+SOC over the 24-week double-blind phase in autoantibody-positive patients with gMG.⁶

Objective

To assess HRQoL over the 24-week double-blind phase of Vivacity-MG3, measured by the Myasthenia Gravis Quality of Life 15-item revised scale (MGQoL-15r) and the EuroQoL 5-Dimension Visual Analogue Scale (EQ-5D-VAS).

Methods

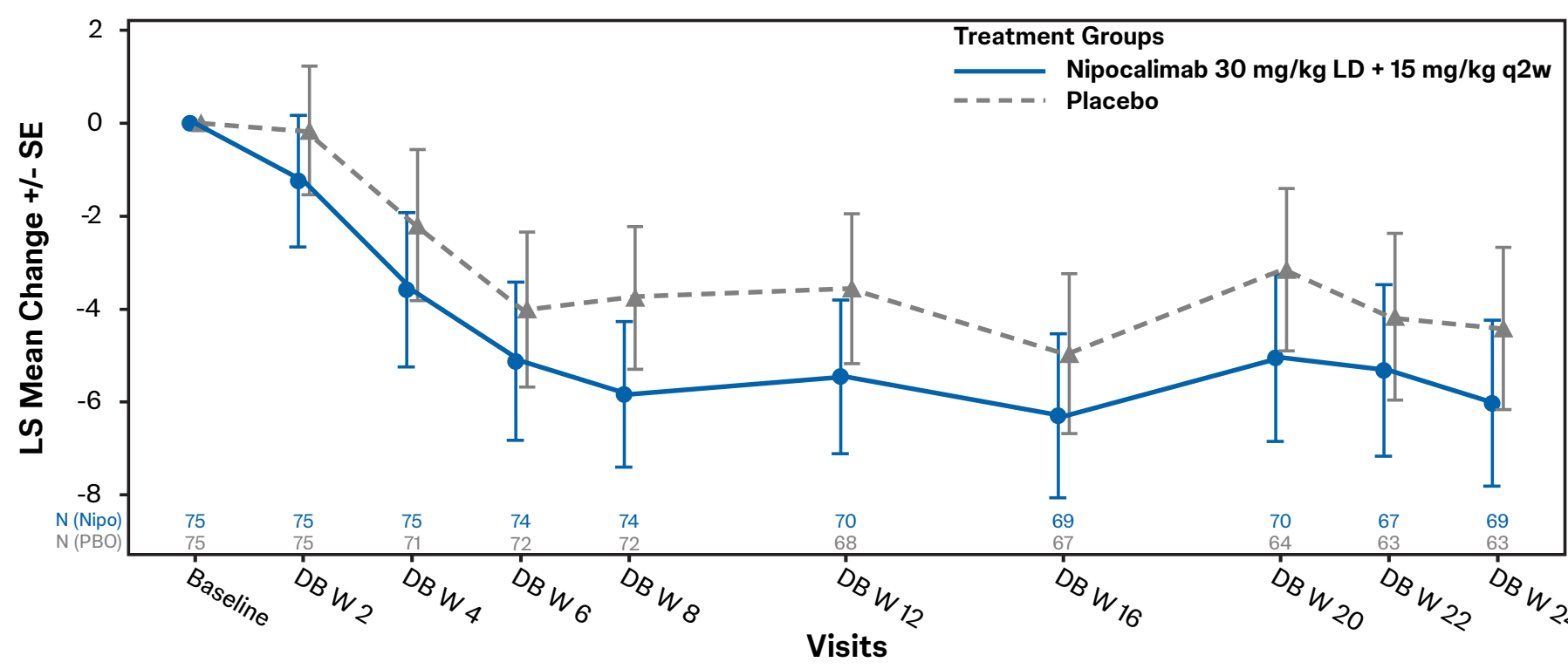
- All HRQoL data were analyzed in the efficacy analysis population that included all patients who received ≥1 dose (partial or complete) of any study intervention in the double-blind phase and were antibody positive for a gMG-related pathogenic antibody (anti-AChR, anti-MuSK, or anti-LRP4).
- Mean change-from-baseline (CFB) between groups in MGQoL-15r and EQ-5D-VAS over 24 weeks were compared using ANCOVA models.
- Meaningful within-person improvement (MWPI) was defined as a change of ≥4-points⁷ on the MGQoL-15r scale and 10-point change in the EQ-5D-VAS.⁸
- Proportion of patients achieving MWPI and time-to-MWPI over 24 weeks were examined using Chi-square test and Kaplan-Meier analyses.
- Logistic regression was used to evaluate the likelihood of achieving MWPI over 24 weeks and sustaining MWPI for ≥8, 12, 16, and 20 weeks between groups.

Results

LS mean change on MGQoL-15r and EQ-5D-VAS

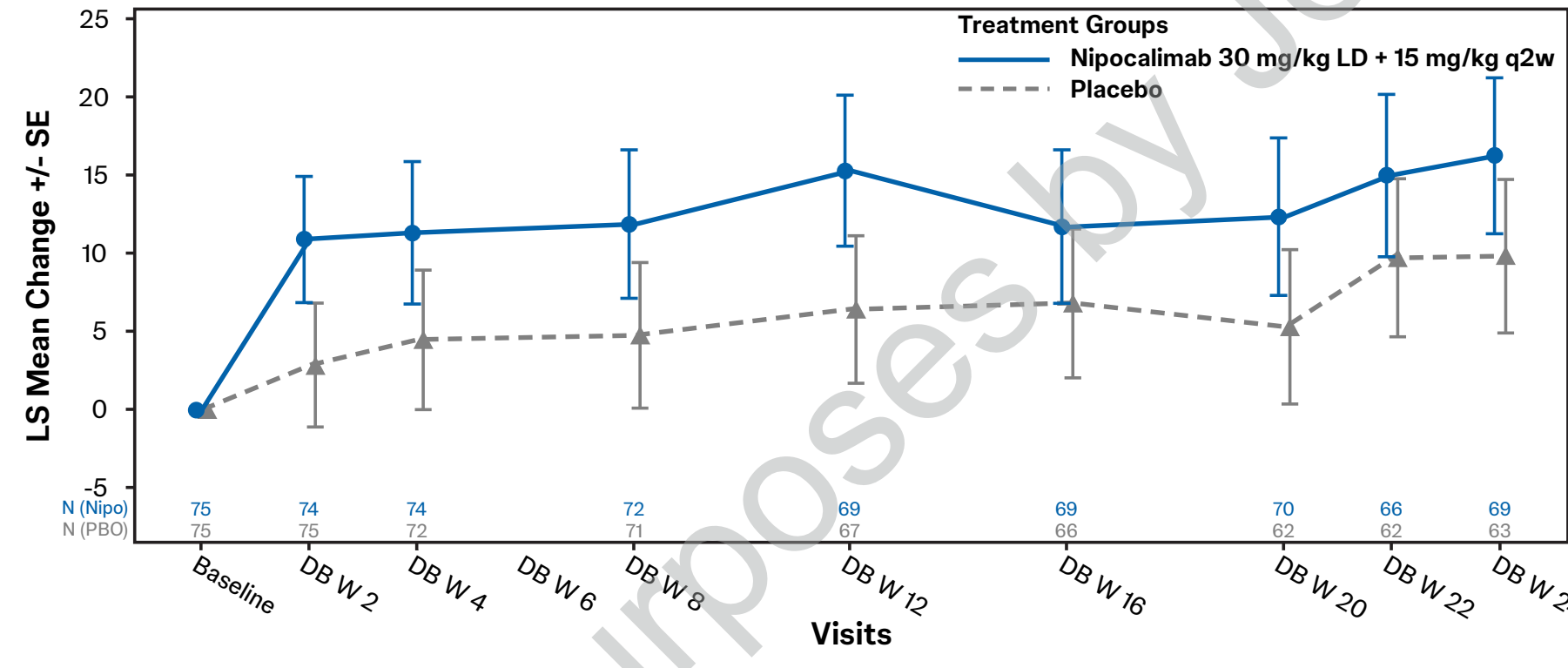
- LS-mean (95% CI) difference in CFB on MGQoL-15r was numerically greater with nipocalimab+SOC versus placebo+SOC (−1.38 [−3.14, 0.37]) at Week 4 and sustained (−1.61 [−3.55, 0.33]) at Week 24 (**Figure 1**).
- LS-mean (95% CI) difference in CFB on EQ-5D-VAS was significantly greater with nipocalimab+SOC versus placebo+SOC (6.86 [2.07, 11.66], p<0.05) at Week 4 and sustained (6.47 [1.05, 11.88], p<0.05) at Week 24 (**Figure 2**).

Figure 1. LS Mean change on MGQoL-15r from baseline over time



MGQoL-15r was used to measure HRQoL; range 0–30; higher scores indicate worse quality of life. DB=double-blind; HRQoL=health-related quality of life; LD=loading dose; LS=least square; MGQoL-15r=Myasthenia Gravis Quality of Life 15-item revised scale; Nipo=nipocalimab; PBO=placebo; q2w=every 2 weeks; SE=standard error; W=week.

Figure 2. LS Mean change on EQ-5D-VAS from baseline over time

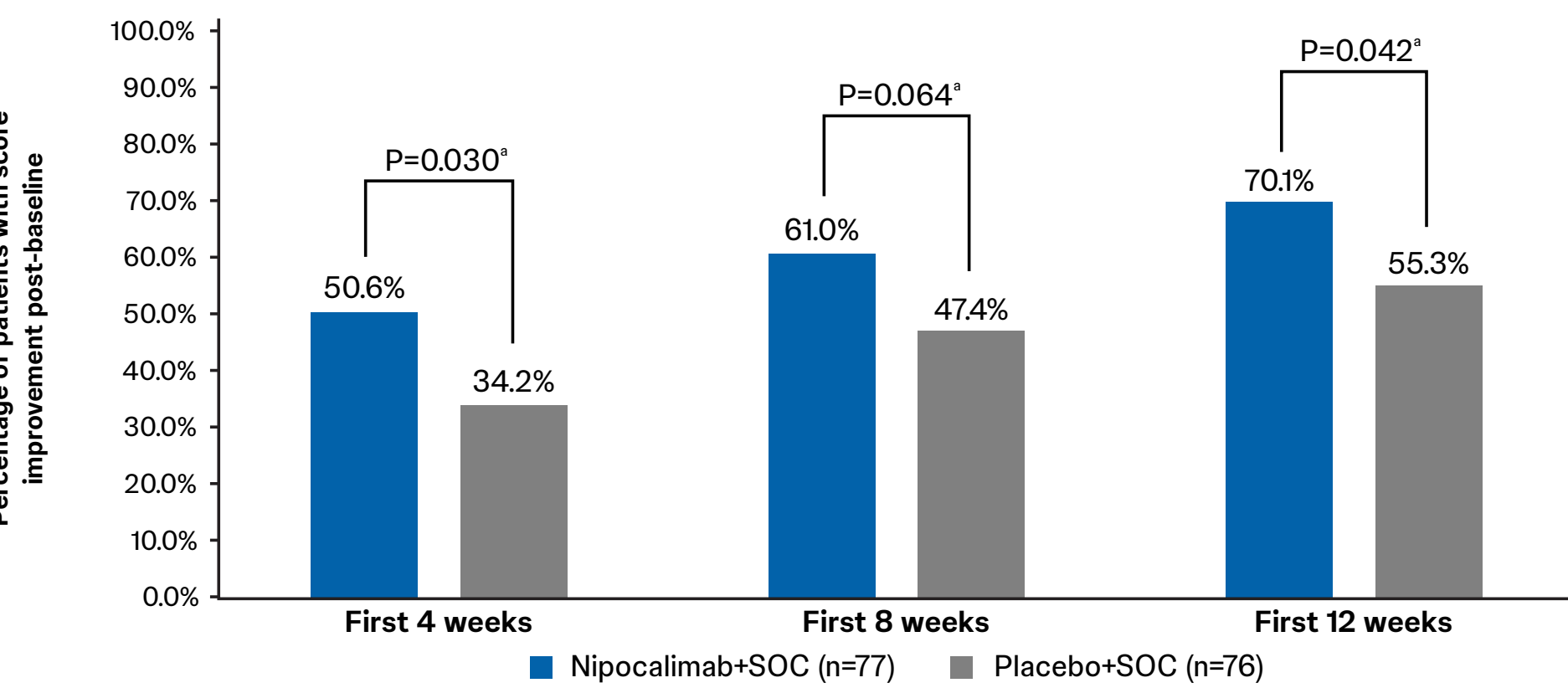


EQ-5D-VAS was used to assess HRQoL; range 0–100; higher scores indicate better health. DB=double-blind; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; HRQoL=health-related quality of life; LD=loading dose; LS=least square; Nipo=nipocalimab; PBO=placebo; q2w=every 2 weeks; SE=standard error; W=week.

Score improvement over time

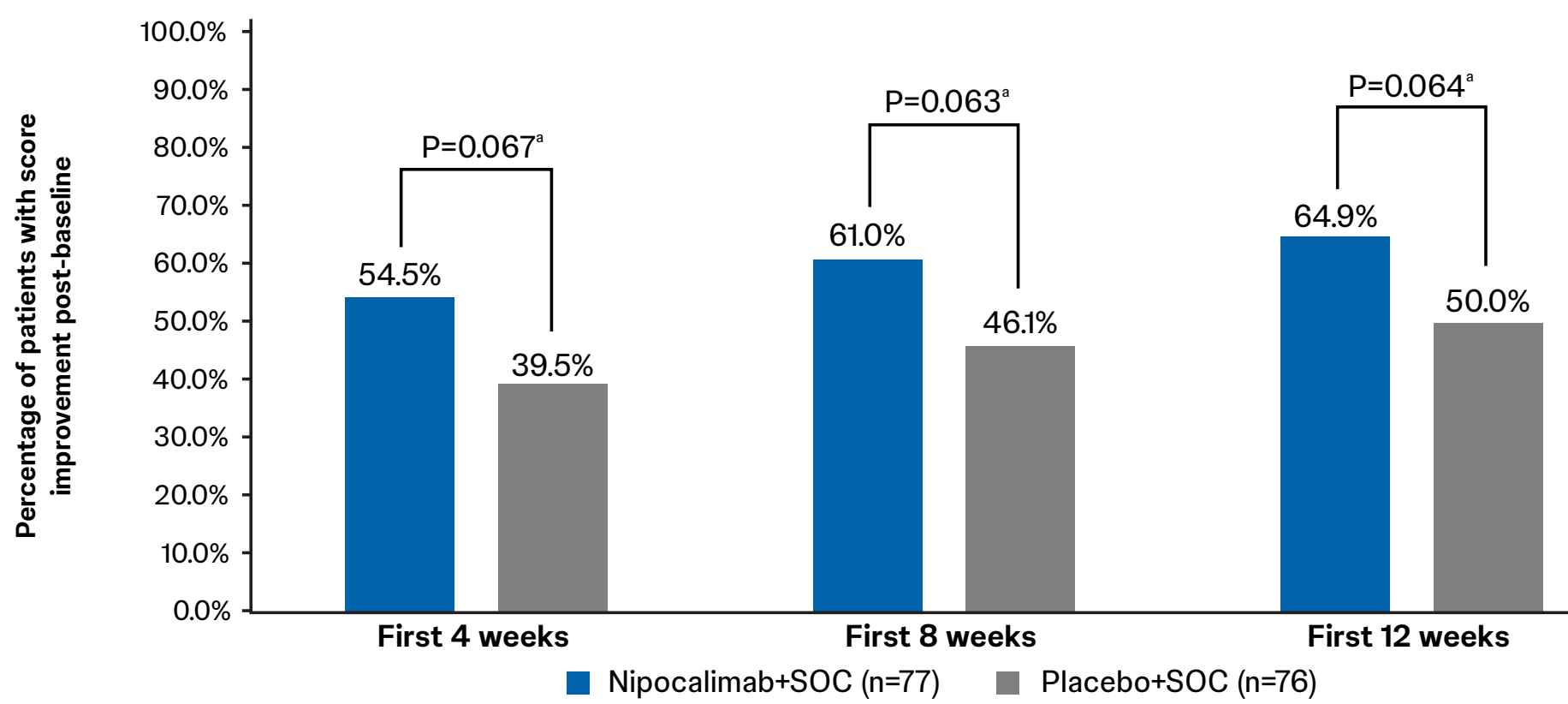
- Across time points, a significantly greater proportion of nipocalimab-treated patients (vs placebo-treated) achieved MWPI on MGQoL-15r scale in the first 4 and 12 weeks of treatment (**Figure 5**).
- Across time points, a numerically greater proportion of nipocalimab-treated patients (vs placebo-treated) achieved MWPI on EQ-5D-VAS scale in the first 4, 8, and 12 weeks of treatment (**Figure 6**).

Figure 5. Patients with MGQoL-15r score improvement post-baseline in first 4, 8, 12 weeks



MGQoL-15r was used to measure HRQoL. DB=double-blind; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; HRQoL=health-related quality of life; MGQoL-15r=Myasthenia Gravis Quality of Life 15-item revised scale; SOC=standard-of-care.

Figure 6. Patients with EQ-5D-VAS score improvement post-baseline in first 4, 8, 12 weeks

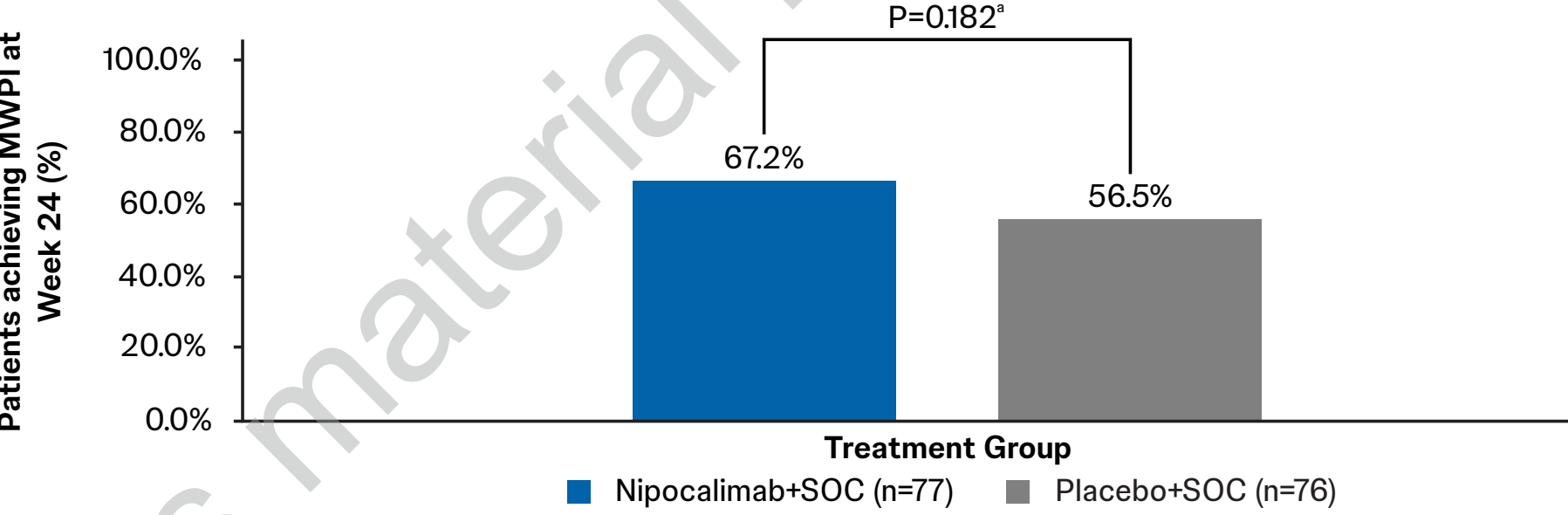


EQ-5D-VAS was used to assess HRQoL. DB=double-blind; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; HRQoL=health-related quality of life; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; HRQoL=health-related quality of life; SOC=standard-of-care.

MWPI in MGQoL-15r and EQ-5D-VAS

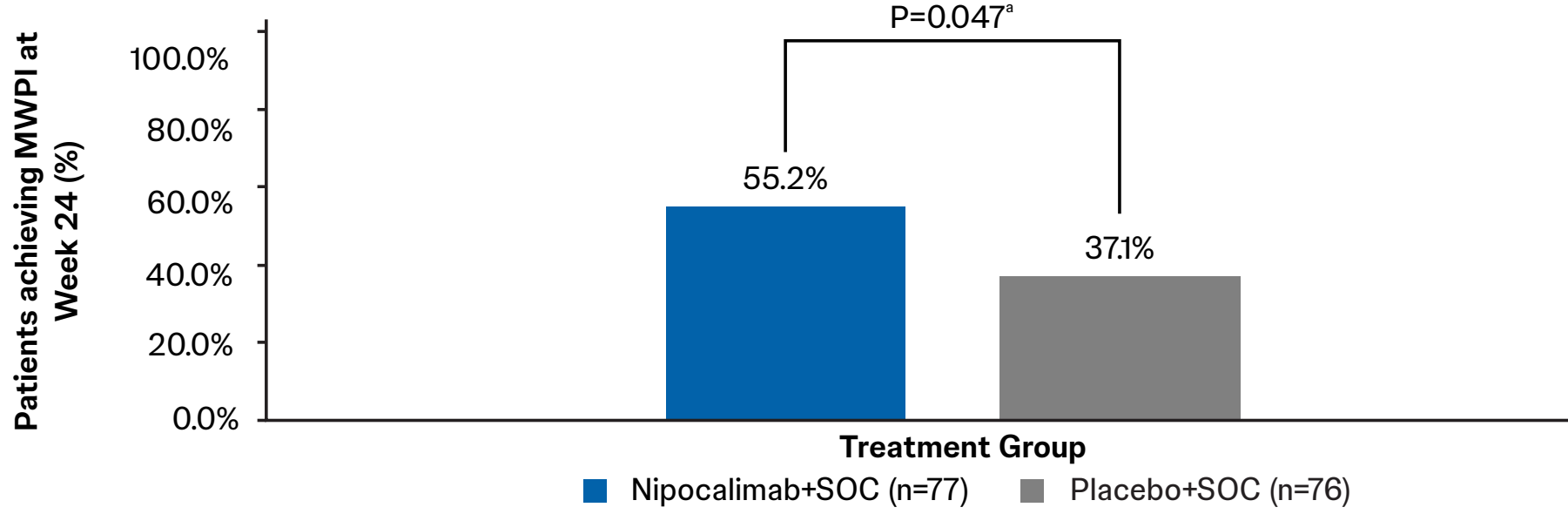
- At 24 weeks, 67.2% (45/67) versus 56.5% (35/62) patients achieved MWPI on MGQoL-15r (absolute difference=10.7%; not significant [ns]) in nipocalimab+SOC versus placebo+SOC (**Figure 3**).
- At 24 weeks, 55.2% (37/67) versus 37.1% (23/62) patients achieved MWPI on EQ-5D-VAS (absolute difference=18.1% [p<0.05], odds ratio 2.15 [95% CI: 1.05, 4.43]) in nipocalimab+SOC versus placebo+SOC (**Figure 4**).
- For both measures, nipocalimab-treated patients were twice more likely to achieve MWPI over 24 weeks with median time-to-response of approximately 4 weeks with nipocalimab+SOC versus 8 weeks with placebo+SOC (p<0.05).

Figure 3. MWPI on MGQoL-15r at 24 weeks



MGQoL-15r was used to measure HRQoL; range 0–30; higher scores indicate worse quality of life. DB=double-blind; HRQoL=health-related quality of life; LD=loading dose; LS=least square; MGQoL-15r=Myasthenia Gravis Quality of Life 15-item revised scale; MWPI=Meaningful within-person improvement; SOC=standard-of-care.

Figure 4. MWPI on EQ-5D-VAS at 24 weeks

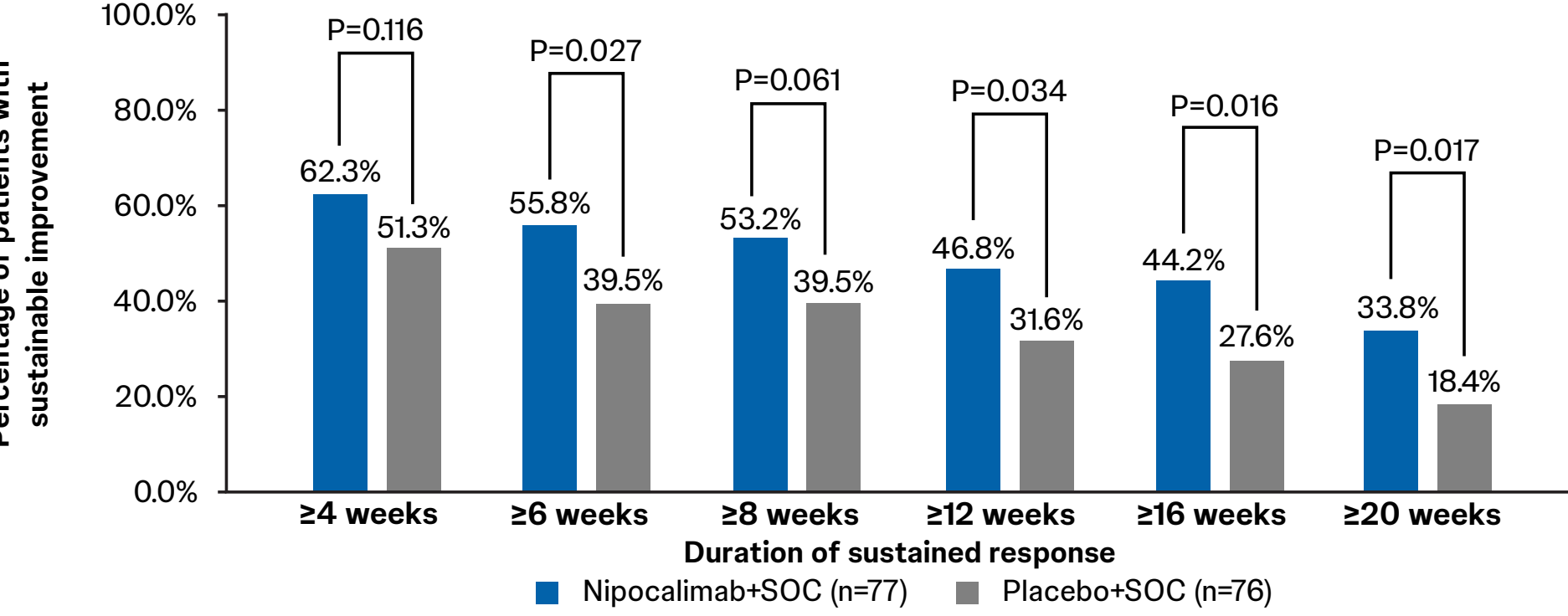


EQ-5D-VAS was used to assess HRQoL; range 0–100; higher scores indicate better health. DB=double-blind; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; HRQoL=health-related quality of life; MWPI=Meaningful within-person improvement; SOC=standard-of-care.

Sustained response on MGQoL-15r and EQ-5D-VAS

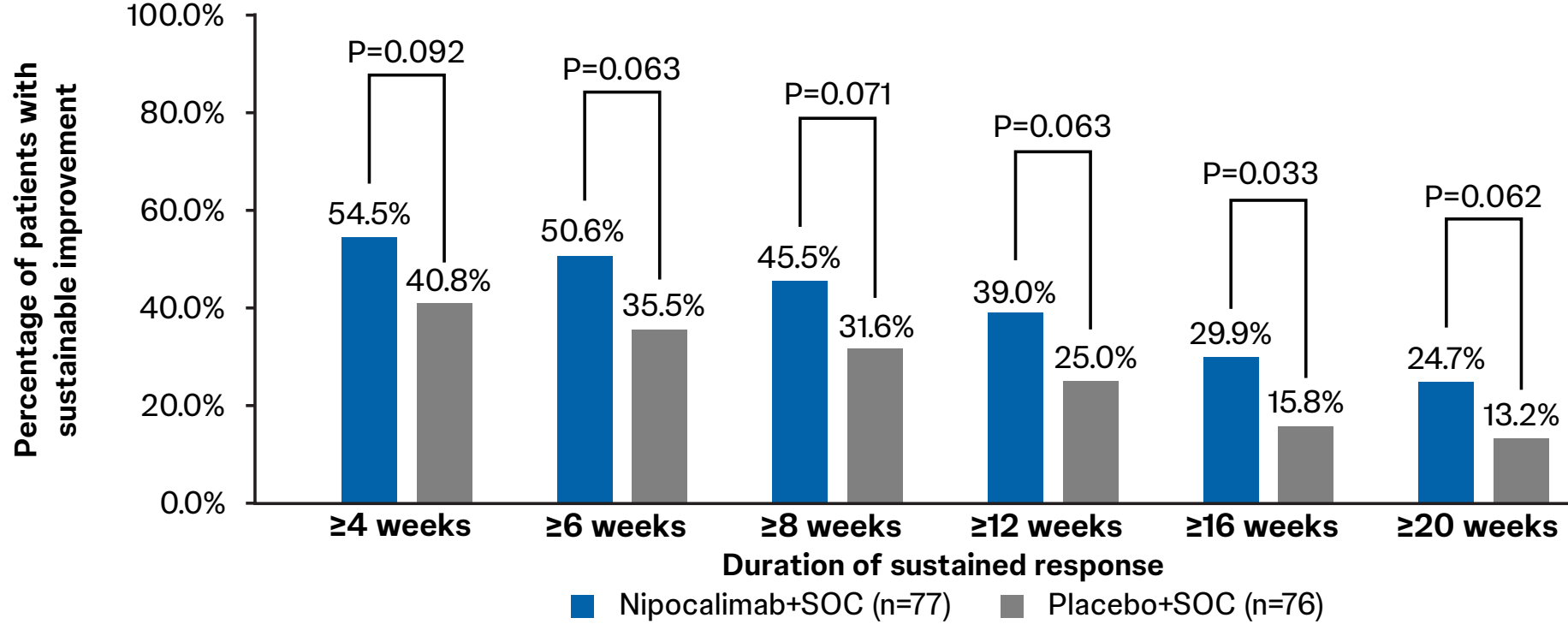
- Across time points, greater proportion of nipocalimab treated patients achieved and sustained MWPI on MGQoL-15r versus patients treated with placebo+SOC, ≥6, 12, 16, 20 weeks; p<0.05 (**Figure 7**).
- Across time points, a numerically greater proportion of nipocalimab treated patients achieved and sustained MWPI on EQ-5D-VAS versus patients treated with placebo+SOC, ≥4, 6, 8, 12, 20 weeks (**Figure 8**).

Figure 7. Sustained MGQoL-15r clinically meaningful score improvement over time



MGQoL-15r was used to measure HRQoL. DB=double-blind; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; HRQoL=health-related quality of life; MGQoL-15r=Myasthenia Gravis Quality of Life 15-item revised scale; SOC=standard-of-care.

Figure 8. Sustained EQ-5D-VAS clinically meaningful score improvement over time



EQ-5D-VAS was used to assess HRQoL. DB=double-blind; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; HRQoL=health-related quality of life; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; HRQoL=health-related quality of life; SOC=standard-of-care.