

Efficacy of Nipocalimab in Patients With Lower Baseline Score of Myasthenia Gravis Activities of Daily Living In Vivacity-MG3 Study

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Introduction

- Generalized myasthenia gravis (gMG) is a chronic autoimmune disease characterized by fluctuating muscle weakness and fatigability, which may worsen without effective treatment¹
 - Nipocalimab is the first approved neonatal Fc receptor (FcRn) blocker for the treatment of gMG in adult and adolescent (≥12 years of age) patients who are anti-acetylcholine receptor positive (AChR) or anti-muscle-specific kinase (MuSK) antibody positive^{2,3}
 - Nipocalimab+standard-of-care (SOC) vs placebo+SOC has demonstrated sustained disease control based on Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores in the 24-week phase 3, double-blind (DB) Vivacity-MG3 study in seropositive patients with gMG^{4,5}
- Least square (LS) mean (standard error [SE]) change over weeks 22, 23, and 24 in
- MG-ADL total score: −4.7 (0.33) vs −3.3 (0.34); difference: −1.45 (0.47); p=0.002
 - QMG total score: −4.9 (0.50) vs −2.1 (0.50); difference: −2.81 (0.71); p<0.001
- However, it is unclear whether patients with lower baseline MG-ADL scores, who may have less severe symptoms, derive similar benefit

Objective

To assess the efficacy of nipocalimab+SOC in a subset of patients with gMG with lower baseline symptom burden (MG-ADL scores: 6–9) in Vivacity-MG3

Results

Baseline demographics

- Baseline demographics were generally balanced between nipocalimab- and placebo-treated patients (Table 1)

Table 1. Baseline characteristics

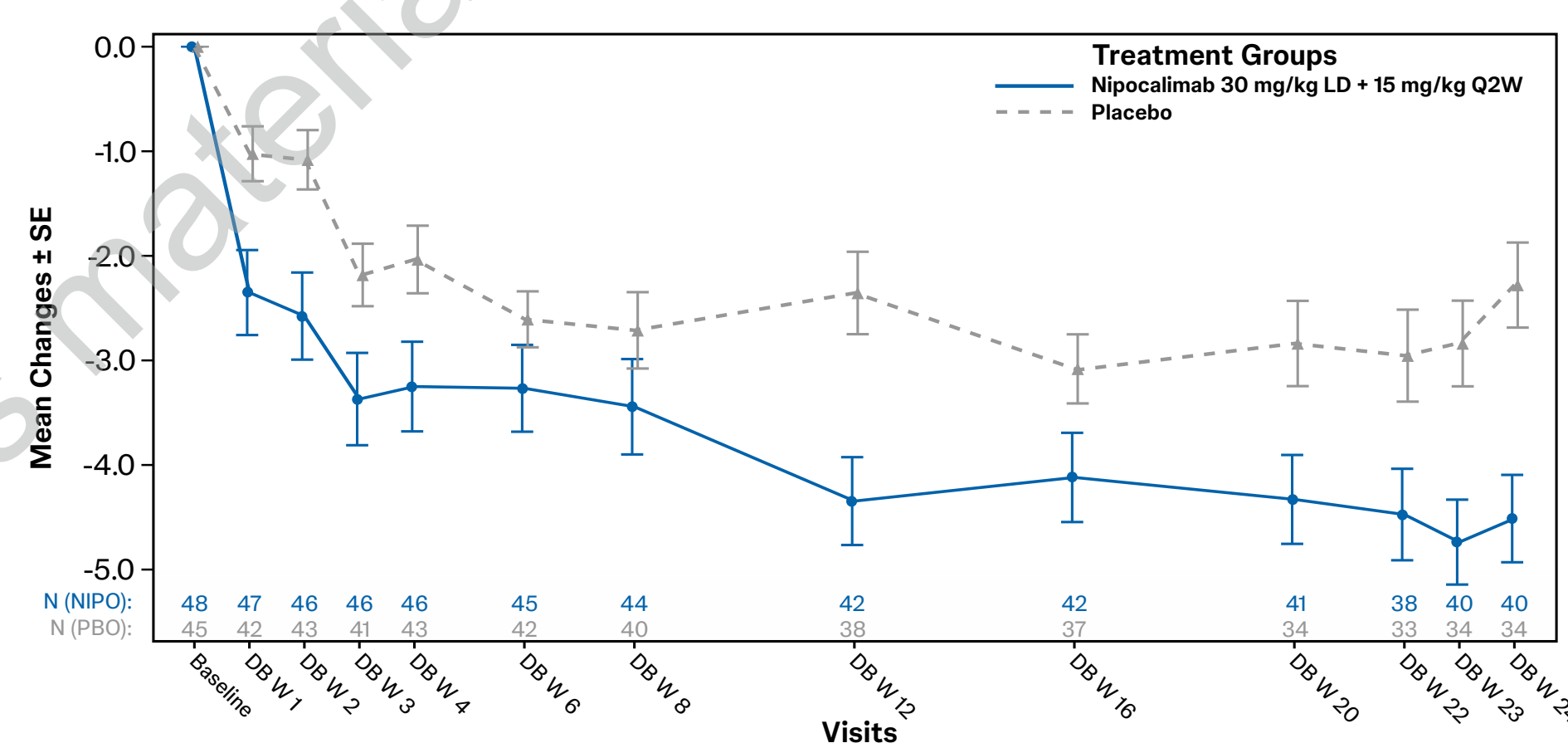
	Baseline MG-ADL total score 6–9	
	Nipocalimab+SOC (n=48)	Placebo+SOC (n=45)
Age, median (range), years	51.0 (20; 81)	47.0 (20; 81)
Female, n (%)	31 (64.6)	26 (57.8)
Race, n (%)		
Asian	18 (37.5)	19 (42.2)
Black or African American	0	1 (2.2)
White	28 (58.3)	24 (53.3)
Not reported	2 (4.2)	1 (2.2)
BMI, median (range), kg/m ²	26.1 (16; 40)	26.3 (16; 41)
Duration of MG, median (range), years	3.0 (0; 25)	7.0 (0; 37)
Age at onset, median (range), years	43.5 (4; 78)	38.0 (7; 78)
Baseline MG-ADL total score, mean (SD)	7.6 (0.87)	7.6 (1.02)
Baseline QMG total score, mean (SD)	13.6 (4.27)	14.9 (5.60)
Antibody-positive at screening, n (%)	48 (100.0)	45 (100.0)
Anti-AChR+	42 (87.5)	43 (95.6)
Anti-MuSK+	6 (12.5)	2 (4.4)
Anti-LRP4+	0	0
MGFA Class, n (%)		
I	1 (2.1)*	0
IIa	5 (10.4)	8 (17.8)
IIb	8 (16.7)	8 (17.8)
IIIa	24 (50.0)	17 (37.8)
IIIb	9 (18.8)	8 (17.8)
IVa	1 (2.1)	4 (8.9)
IVb	0	0

*Patient had MGFA class IIa at screening and MG-ADL of 8 at both screening and baseline. AChR=acetylcholine receptor, BMI=body mass index, LRP4=low-density lipoprotein receptor-related protein 4, MG=myasthenia gravis, MG-ADL=Myasthenia Gravis-Activities of Daily Living, MGFA=Myasthenia Gravis Foundation of America, MuSK=muscle-specific kinase, QMG=Quantitative Myasthenia Gravis, SD=standard deviation, SOC=standard-of-care.

MG-ADL Total Score: Change from baseline over time

- At week 24, mean (standard deviation [SD]) total scores were: nipocalimab+SOC: 3.2 (2.56); placebo+SOC: 5.3 (2.42)
- Across the 24 week treatment period, patients receiving nipocalimab+SOC demonstrated consistently greater reductions in MG-ADL total scores compared with placebo+SOC (Figure 2)

Figure 2. Mean (SE) change in baseline MG-ADL total score over time



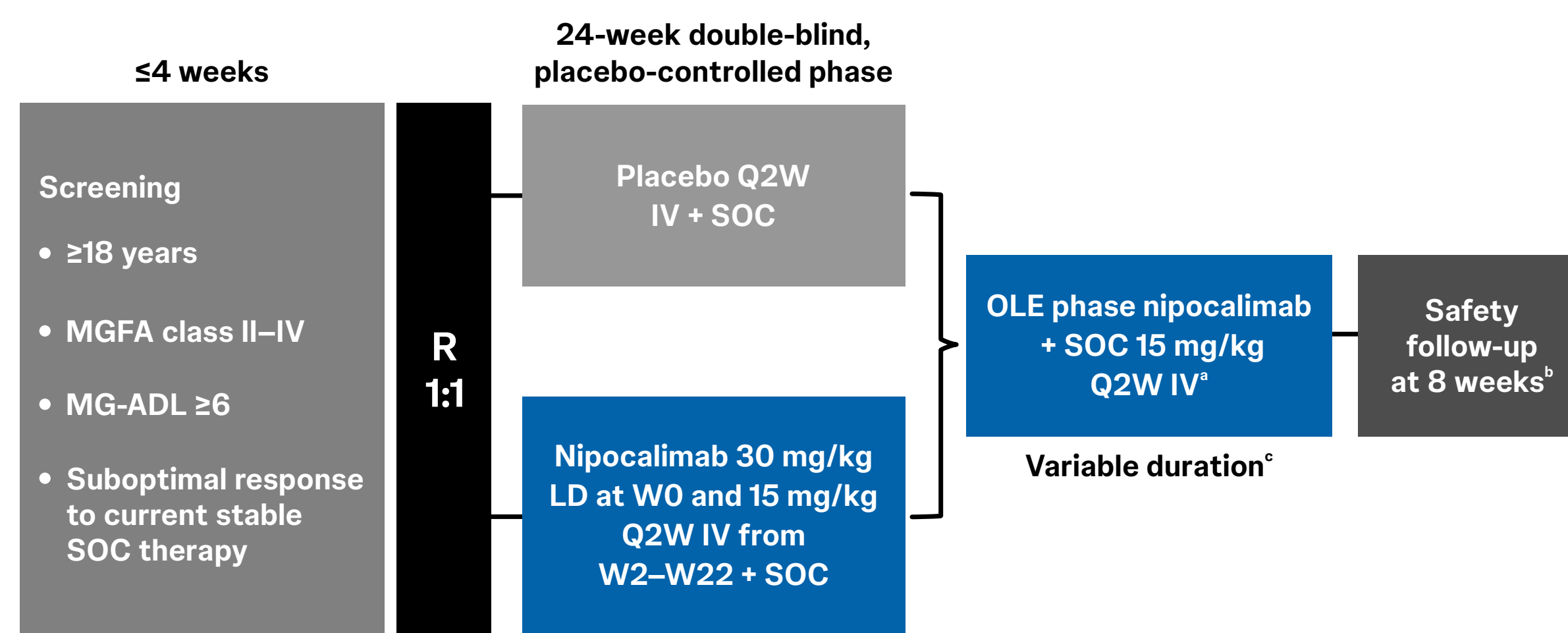
DB=double-blind, LD=loading dose, MG-ADL=Myasthenia Gravis-Activities of Daily Living, NIPO=nipocalimab, PBO=placebo, Q2W=every 2 weeks, SE=standard error, W=week.

Methods

Analysis population

- Patients with gMG and lower baseline symptom burden from efficacy analysis set of Vivacity-MG3 study (Figure 1)
 - All patients who received ≥1 dose of nipocalimab+SOC or placebo+SOC in the DB phase and were antibody positive for a gMG-related pathogenic antibody (anti-AChR, anti-MuSK, or anti-LRP4) with baseline MG-ADL score below cohort median score of 9 (total score 6–9)

Figure 1. Study design⁴

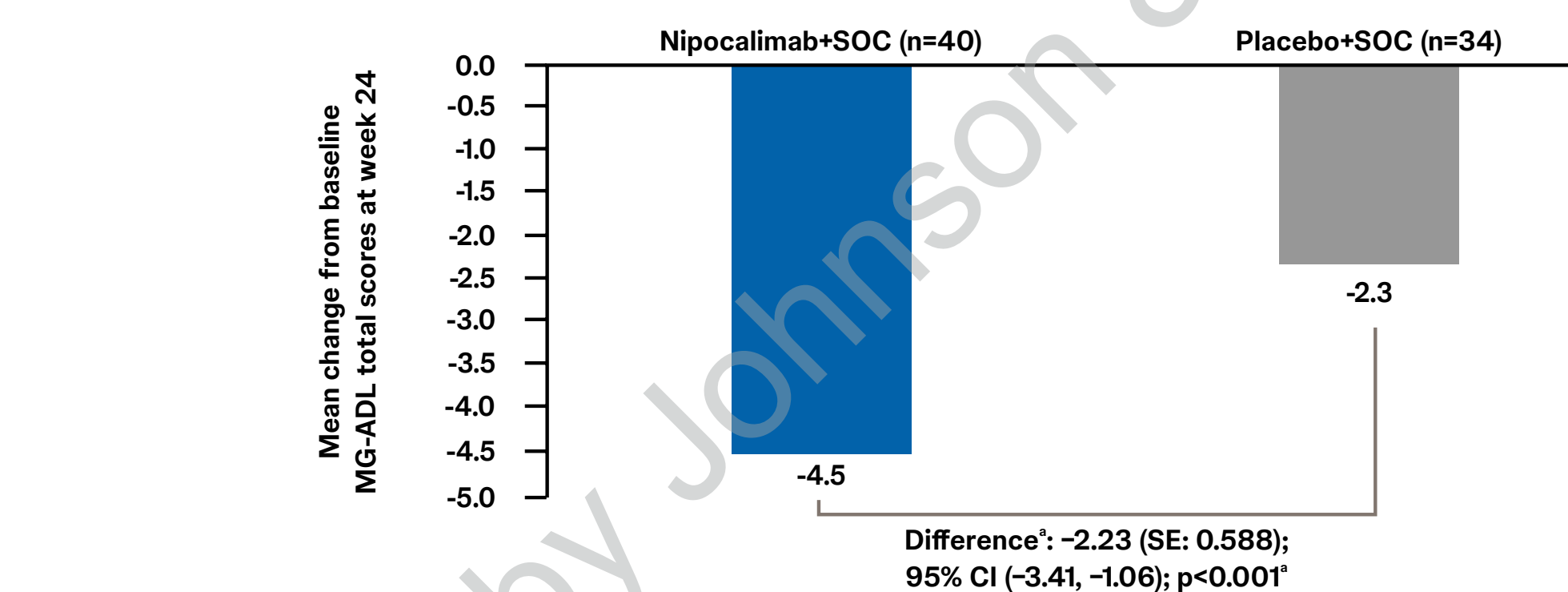


⁴Due to the COVID-19 pandemic, some participants from the Phase 2 study (NCT03772587) were unable to enter the Phase 2 OLE study (NCT03896295). These participants could directly enter the Phase 3 OLE and their data will be disclosed later. *Participants who withdrew or discontinued after receiving any amount of study intervention are required to complete a safety follow-up visit 8 weeks after their last dose. *In the EU, the OLE phase will be up to 240 weeks. COVID-19=coronavirus disease 2019, EU=European Union, IV=intravenous, LD=loading dose, MG-ADL=Myasthenia Gravis-Activities of Daily Living, MGFA=Myasthenia Gravis Foundation of America, OLE=open-label extension, Q2W=every 2 weeks, R=randomized, SOC=standard-of-care, W=week.

MG-ADL Total Score: Mean change from baseline

- At week 24, mean (SD) change in baseline total score were, nipocalimab+SOC: −4.5 (2.64) versus placebo+SOC: −2.3 (2.37)
- Difference: −2.23 (SE: 0.588); 95% CI (−3.41, −1.06); p<0.001 (Figure 3)

Figure 3. Mean change from baseline to week 24 in MG-ADL total score

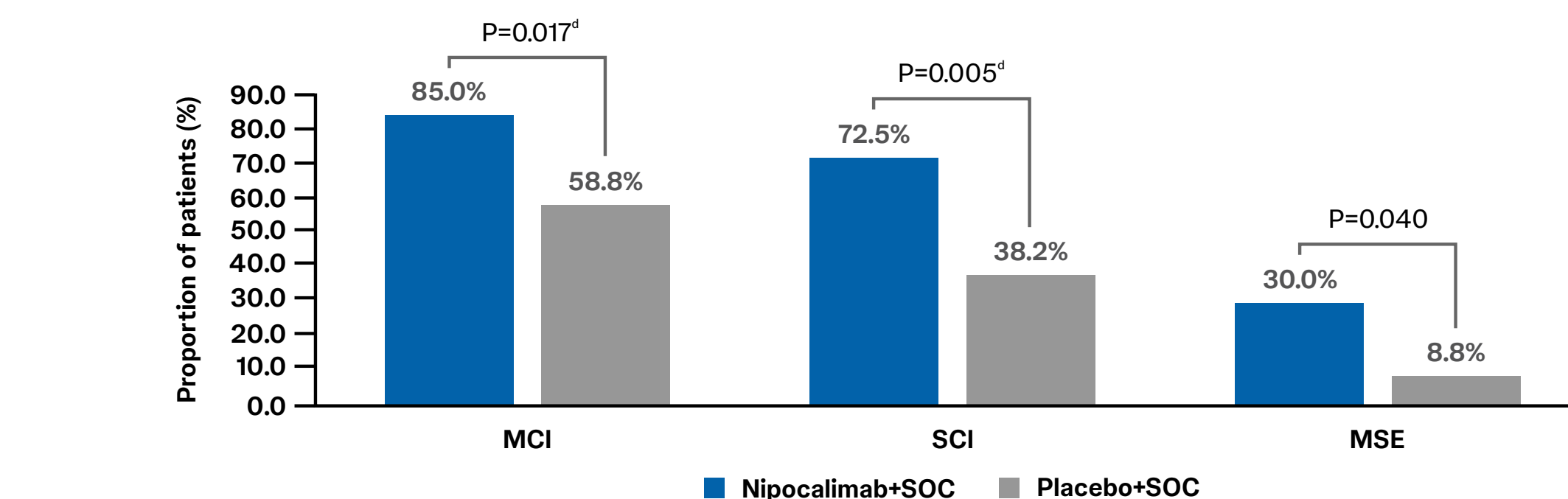


*Calculated from two-sample t-test comparing MG-ADL total score change from baseline between treatments. CI=confidence interval, MG-ADL=Myasthenia Gravis-Activities of Daily Living, SE=standard error, SOC=standard-of-care.

MG-ADL: MCI, SCI and MSE

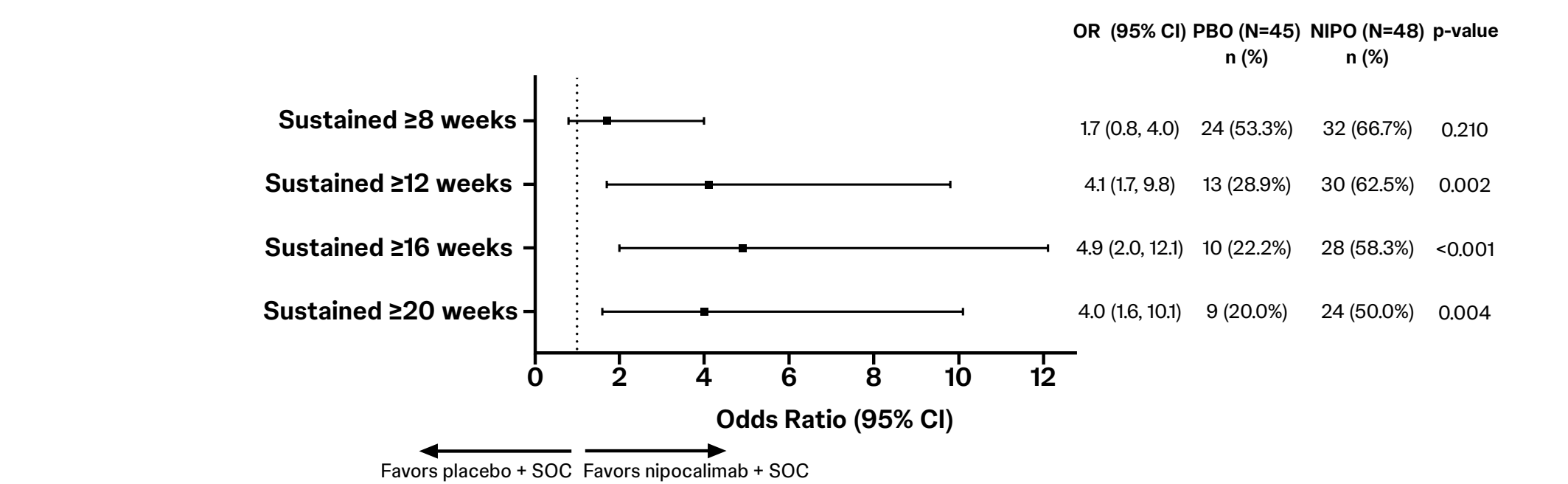
- At week 24, a greater proportion of nipocalimab+SOC patients met MCI, SCI and MSE criteria for MG-ADL total scores versus placebo+SOC (Figure 4)
- Patients treated with nipocalimab+SOC had 4 times greater odds of achieving MCI compared with patients treated with placebo+SOC over 24 weeks
 - Unstratified OR ratio (95% CI): 4.0 (1.3, 12.0); p=0.017
- Significantly greater proportion of nipocalimab+SOC patients sustained MCI for ≥12, 16, and 20 weeks, compared with patients treated with placebo+SOC (Figure 5)
- Patients treated with nipocalimab+SOC had 4.3 times greater odds of achieving SCI compared with patients treated with placebo+SOC over 24 weeks
 - Unstratified OR ratio (95% CI): 4.3 (1.6, 11.3); p=0.005
- Patients treated with nipocalimab+SOC had 4.4 times greater odds of achieving MSE compared with patients treated with placebo+SOC over 24 weeks
 - Unstratified OR (95% CI): 4.4 (1.1, 17.3); p=0.004

Figure 4. Proportion of patients achieving MG-ADL MCI^a, SCI^b and MSE^c from baseline to week 24



^aDefined as MG-ADL total score improvement of ≥2 points from baseline. ^bDefined as MG-ADL total score improvement of ≥3 points from baseline. ^cDefined as a post-baseline MG-ADL total score of 0 or 1. *Calculated from Fisher's exact test. MCI=meaningful clinical improvement, MG-ADL=Myasthenia Gravis-Activities of Daily Living, MSE=minimum symptom expression, NIPO=Nipocalimab, OR=odds ratio, PBO=placebo, SOC=standard-of-care.

Figure 5. Sustained^a MG-ADL MCI improvements from baseline to week 24

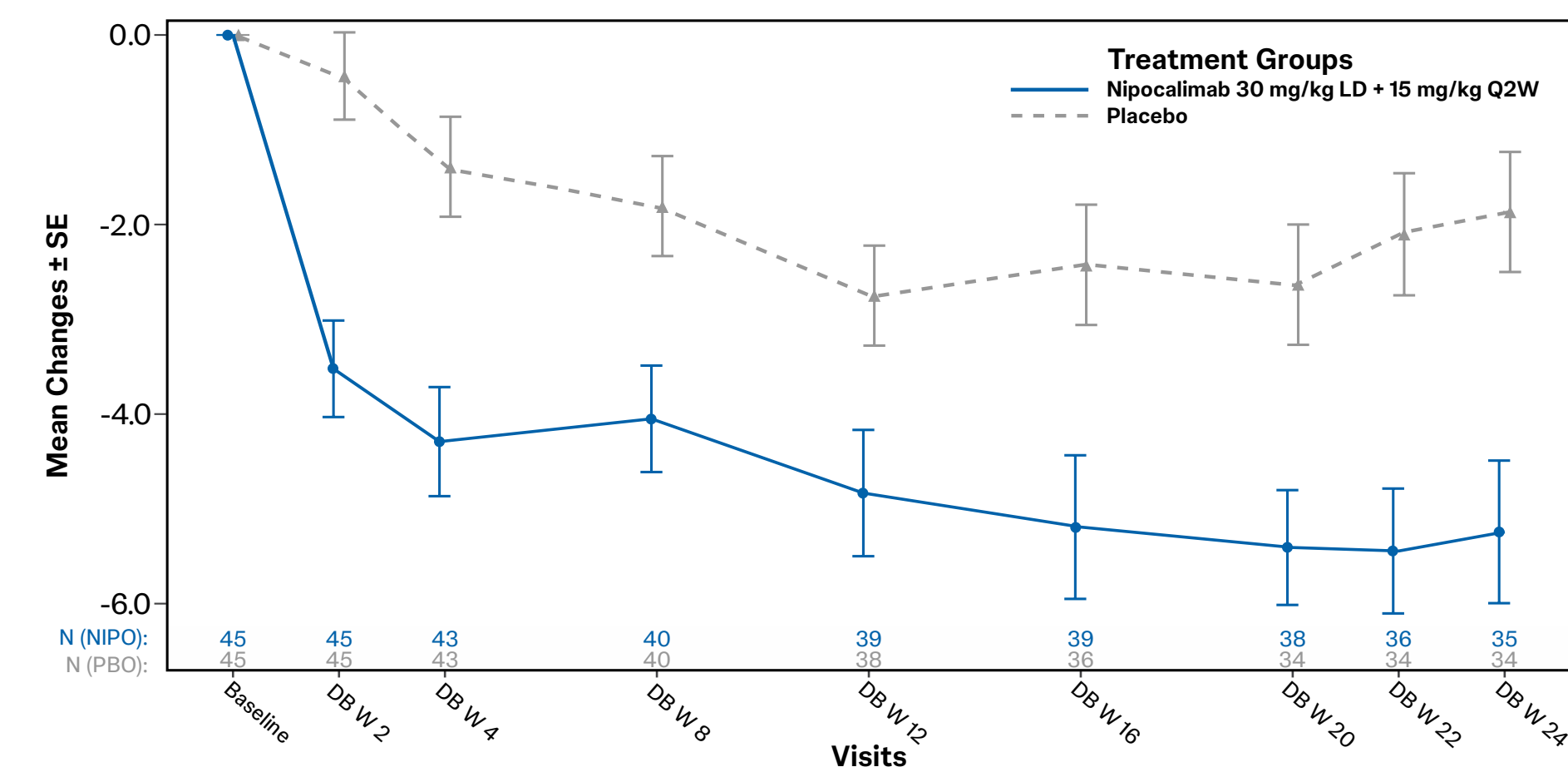


^aLongest uninterrupted duration of improvement. CI=confidence interval, MCI=meaningful clinical improvement, MG-ADL=Myasthenia Gravis-Activities of Daily Living, MSE=Minimum symptom expression, NIPO=Nipocalimab, OR=odds ratio, PBO=placebo, SOC=standard-of-care.

QMG Total Score: Change from baseline over time

- At week 24, mean (SD) total scores were: nipocalimab+SOC: 9.1 (5.65); placebo+SOC: 12.9 (6.55)
- Across the 24-week treatment period, patients receiving nipocalimab+SOC demonstrated consistently greater reductions in QMG total scores compared with placebo+SOC (Figure 6)

Figure 6. Mean (SE) change in baseline QMG score over time during DB phase

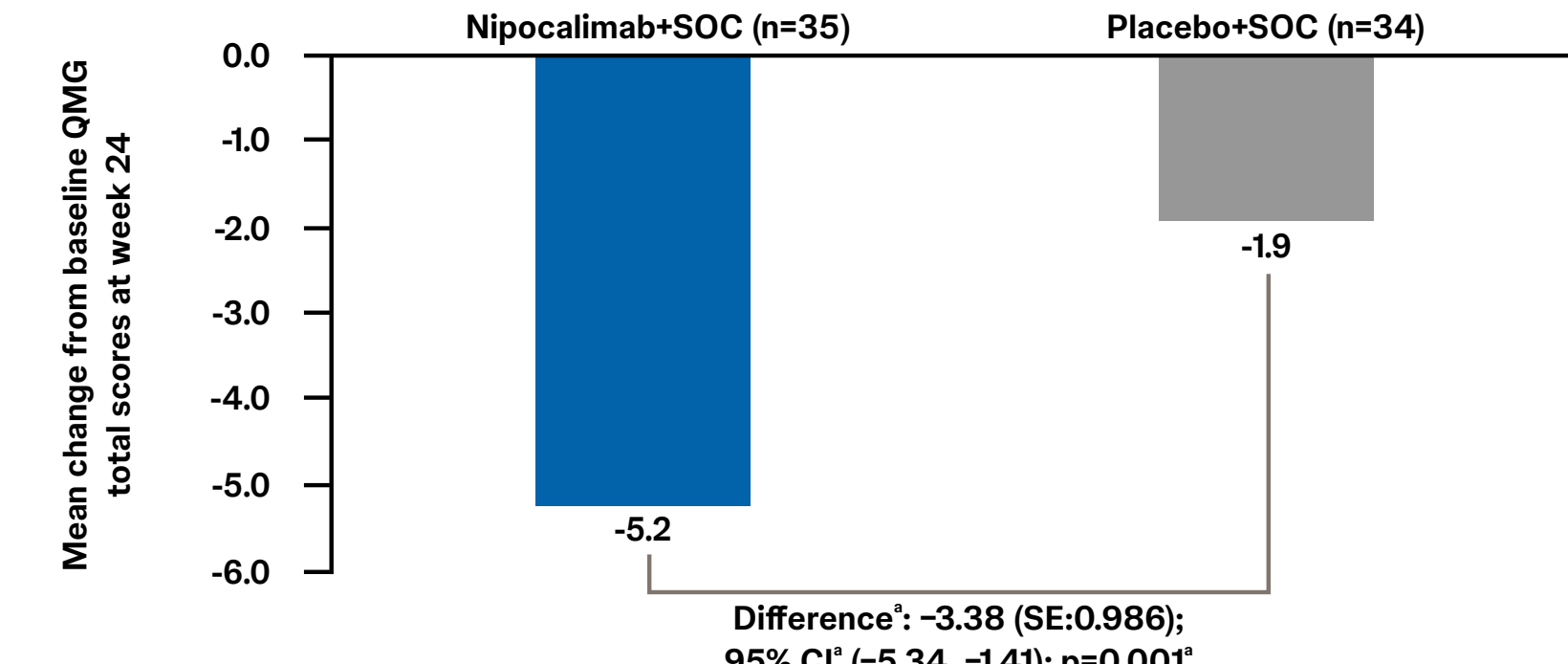


DB=double-blind, LD=loading dose, NIPO=Nipocalimab, PBO=placebo, Q2W=every 2 weeks, QMG=Quantitative Myasthenia Gravis, SE=standard error, W=week.

QMG Total Score: Mean change from baseline

- At week 24, Mean (SD) change from baseline score were nipocalimab+SOC: −5.2 (4.45); placebo+SOC: −1.9 (3.69)
- Difference: −3.38 (SE: 0.986); 95% CI (−5.34, −1.41); p=0.001 (Figure 7)

Figure 7. Mean change from baseline to week 24 in QMG total score

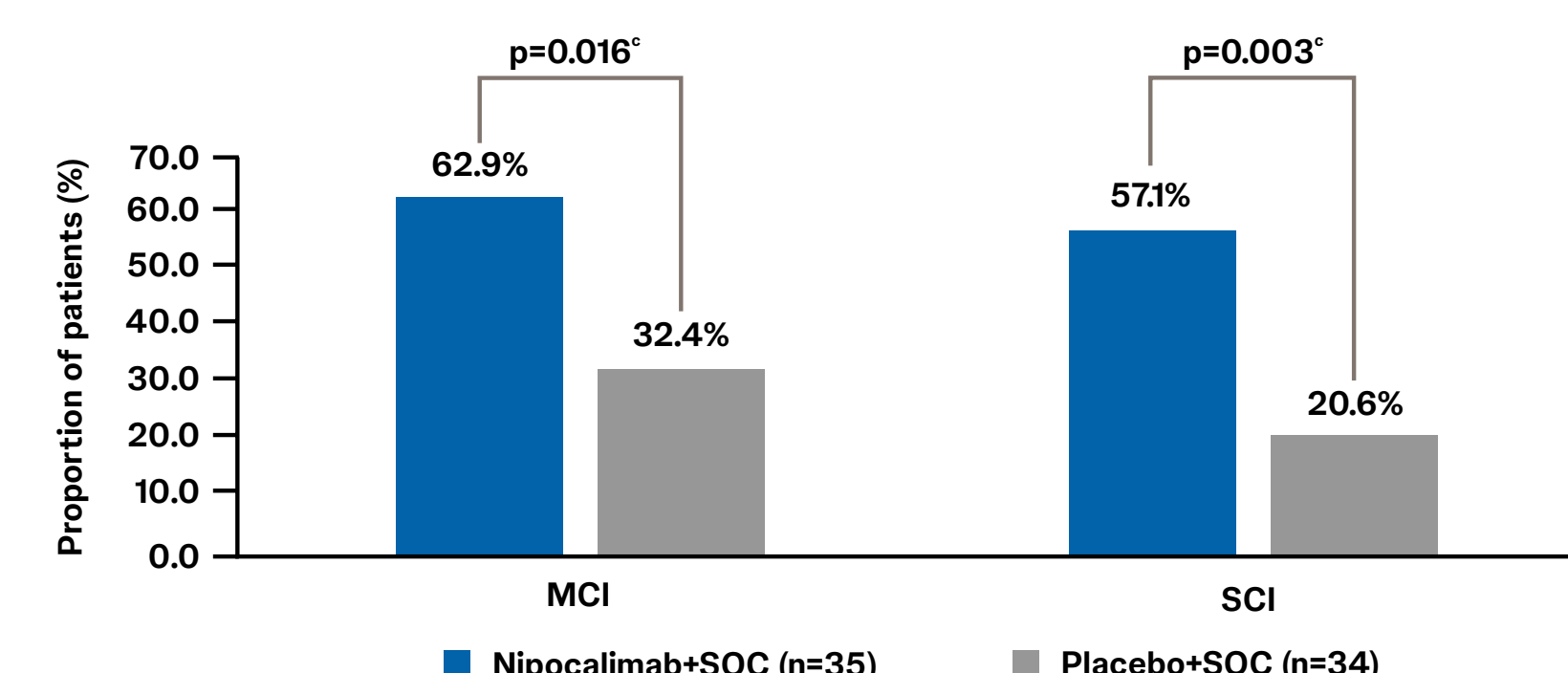


*Calculated from two-sample t-test comparing QMG total score change from baseline between treatments. CI=confidence interval, QMG=Quantitative Myasthenia Gravis, SE=standard error, SOC=standard-of-care.

QMG: MCI and SCI

- At week 24, a greater proportion of nipocalimab+SOC patients met MCI and SCI criteria for QMG total scores versus placebo+SOC (Figure 8)
- Patients treated with nipocalimab+SOC had 3.5 times greater odds of achieving MCI compared with patients treated with placebo+SOC over 24 weeks
 - Unstratified OR ratio (95% CI): 3.5 (1.3, 9.6), p=0.016
- Patients treated with nipocalimab+SOC had 5.1 times greater odds of achieving SCI compared with patients treated with placebo+SOC over 24 weeks
 - Unstratified OR ratio (95% CI): 5.1 (1.8, 15.0), p=0.003

Figure 8. Proportion of patients achieving QMG MCI-3^a and SCI-4^b from baseline to week 24



^aDefined as QMG total score improvement of ≥3 points from baseline. ^bDefined as QMG total score improvement of ≥4 points from baseline. *Calculated from Fisher's exact test. MCI=meaningful clinical improvement, QMG=Quantitative Myasthenia Gravis, SCI=substantial clinical improvement, SOC=standard-of-care.