

Effect of Nipocalimab on Sustained Disease Control in Anti-Muscle-Specific Tyrosine Kinase-Antibody Positive Patients With Generalized Myasthenia Gravis: A Post Hoc Analysis of the Vivacity-MG3 Study

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Key Takeaways

- ✓ Nipocalimab demonstrated sustained disease control in the difficult-to-treat subgroup of anti-MuSK antibody-positive patients with gMG
- ✓ At 24 weeks, a greater proportion of anti-MuSK antibody-positive patients treated with nipocalimab achieved meaningful and sustained clinical improvements in MG-ADL and QMG total scores compared to those treated with placebo
- ✓ Safety findings were generally comparable to observations in the overall seropositive gMG population tested in Vivacity-MG3
- ✓ Interpretation of these findings are limited by the small sample size of the anti-MuSK antibody-positive patients

Limitations

- All 4 placebo-treated patients completed 24 weeks of follow-up; their continued participation may reflect differences in clinical care, adherence, or unmeasured health status, introducing potential survivor/selection bias

Introduction

- The pathogenesis of generalised myasthenia gravis (gMG) is primarily linked to anti-acetylcholine receptor (anti-AChR) antibody-mediated disruption of neuromuscular junction; however, antibodies to anti-muscle-specific tyrosine kinase (anti-MuSK) are causative in nearly 8% of all patients with gMG^{1,4}
- MuSK-gMG is characterized by atypical clinical presentation, diagnostic inconsistencies and a more severe phenotype versus AChR-gMG, with an early bulbar involvement, higher frequency of respiratory crisis and poor response to standard treatments⁴
- Nipocalimab is the first approved neonatal Fc receptor (FcRn) blocker for the treatment of both adult and adolescent (≥12 years of age) patients with gMG who are anti-AChR or anti-MuSK antibody-positive^{5,6}
- In the phase 3 Vivacity-MG3 study, nipocalimab, added to standard-of-care (SOC), demonstrated rapid and sustained disease control over 24 weeks in seropositive patients with gMG^{7,8}
- In this post hoc analysis, we report the efficacy of nipocalimab+SOC in a subgroup of anti-MuSK antibody-positive patients with gMG

Objective

To evaluate the efficacy of nipocalimab+SOC versus placebo+SOC in anti-MuSK antibody-positive patients in the Vivacity-MG3 study

Results

Baseline demographics

- A total of 16 patients (nipocalimab+SOC: n=12; placebo+SOC: n=4) were anti-MuSK antibody-positive
- Overall, the majority of patients were females in both groups and patients in the nipocalimab+SOC group (vs placebo+SOC) were older (Table 1)
- Baseline MG-ADL and QMG total scores were generally comparable between the treatment groups

Table 1. Demographics and baseline characteristics (MuSK+ analysis set)

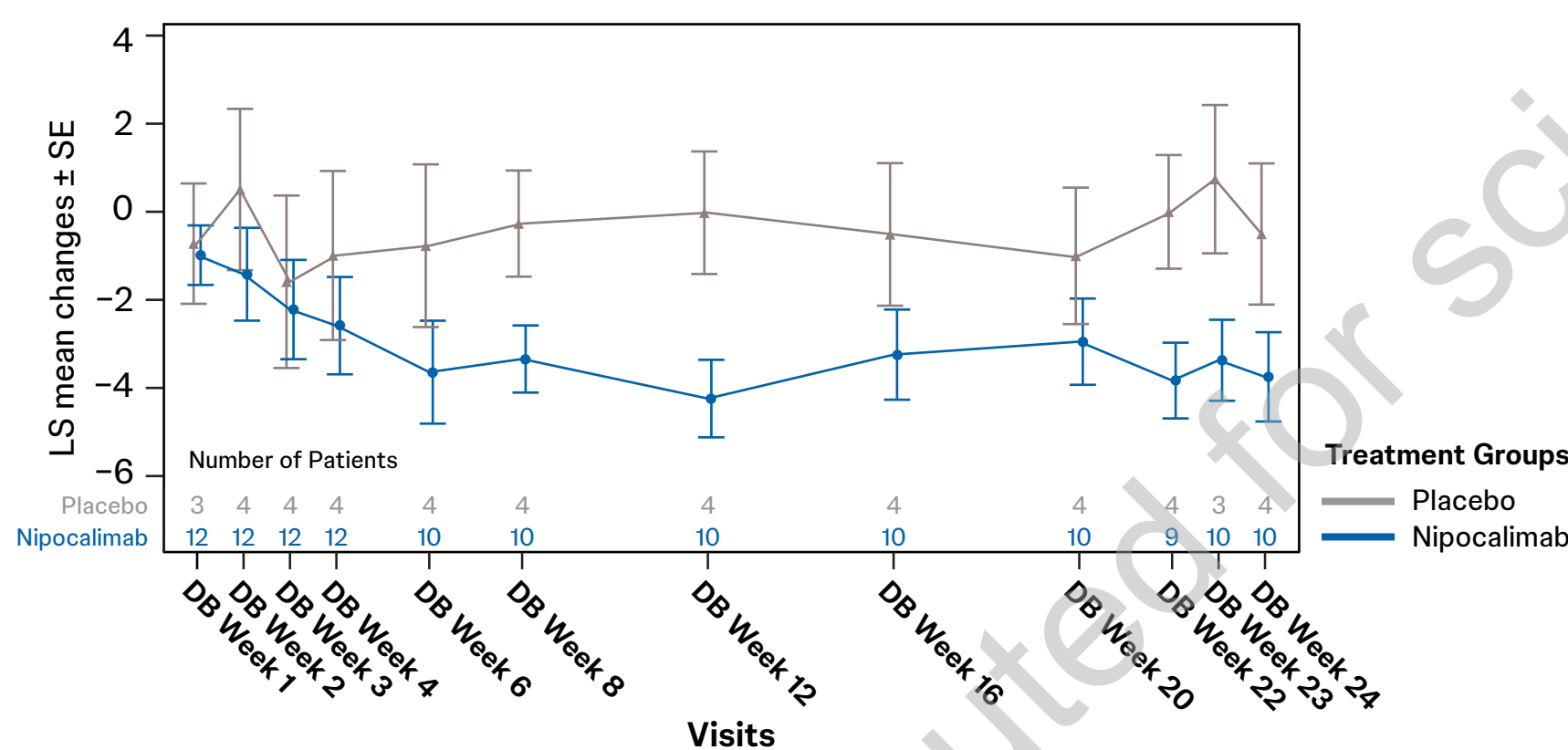
	Nipocalimab+SOC (n=12)	Placebo+SOC (n=4)
Age, median (range), years	56.5 (27–77)	36.5 (32–43)
Female, n (%)	10 (83.3)	4 (100.0)
Race, n (%)		
Asian	6 (50.0)	2 (50.0)
White	5 (41.7)	2 (50.0)
American Indian or Alaska Native	1 (8.3)	0
Duration of MG, mean (SD), years*	8.7 (11.66)	8.5 (4.65)
Age at onset, median (range), years*	47.0 (25–74)	28.0 (26–33)
Baseline MG-ADL total score, mean (SD)	9.8 (3.17)	9.0 (3.24)
Baseline QMG total score, mean (SD)	15.6 (6.02)	18.8 (4.84)
Antibody-positive at screening, n (%)		
Seropositive-MuSK+	12 (100.0)	4 (100.0)
MGFA classes, n (%)		
I	0	0
Ila	1 (8.3)	1 (25.0)
Ilb	2 (16.7)	0
Illa	5 (41.7)	0
IIb	2 (16.7)	3 (75.0)
IVa	0	0
IVb	2 (16.7)	0

*Nipocalimab+SOC, n=11. MG=myasthenia gravis. MG-ADL=Myasthenia Gravis-Activities of Daily Living. MGFA=Myasthenia Gravis Foundation of America. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. QMG=Quantitative Myasthenia Gravis. SD=standard deviation. SOC=standard-of-care.

MG-ADL total score: Change from baseline over time

- At Week 24, mean (SD) MG-ADL total scores were: nipocalimab+SOC: 5.3 (4.32) vs placebo+SOC: 8.5 (3.11)
- Across the 24-week treatment period, patients receiving nipocalimab+SOC showed consistently greater reductions in MG-ADL total scores compared with placebo+SOC (Figure 1)

Figure 1. LS (mean) change from baseline in MG-ADL total score over time (MuSK+ analysis set)

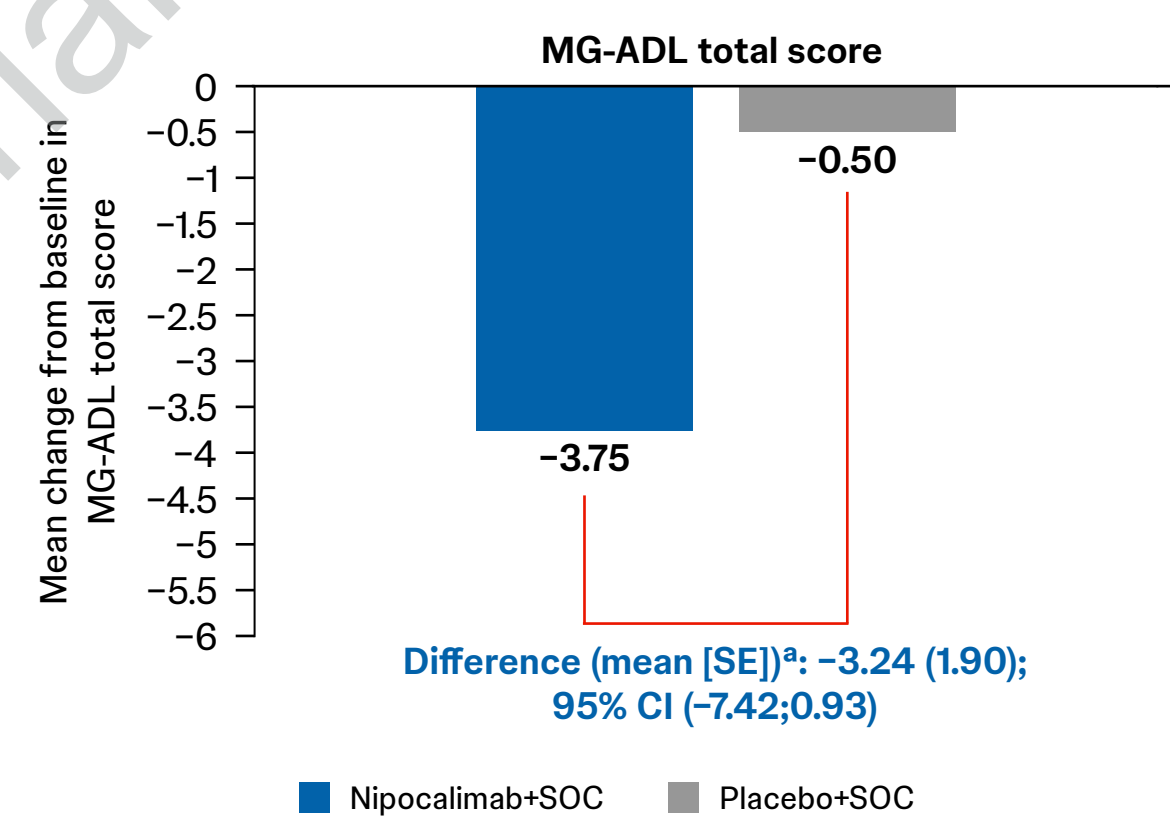


DB=double-blind, LS mean=least-squares mean, MG-ADL=Myasthenia Gravis-Activities of Daily Living. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. SE=standard error, SOC=standard-of-care.

MG-ADL total score: Mean change from baseline

- At Week 24, mean (SD) change from baseline in MG-ADL total scores were: nipocalimab+SOC: -3.75 (3.55) vs placebo+SOC: -0.50 (0.71) (Figure 2)

Figure 2. Mean change from baseline to Week 24 in MG-ADL (MuSK+ analysis set)



*Based on ANCOVA model with treatment group as factor and baseline MG-ADL total score as the covariate. MG-ADL=Myasthenia Gravis-Activities of Daily Living. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. SE=standard error, SOC=standard-of-care.

Methods

Analysis population

- All patients with gMG who were anti-MuSK antibody-positive and received ≥1 dose of nipocalimab+SOC or placebo+SOC during the double-blind phase of Vivacity-MG3 were included in this post hoc analysis⁷

Endpoints

- Mean change from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) total scores at Week 24
- Proportion of patients achieving a meaningful within-patient change: meaningful clinical improvement (MCI) (defined as a ≥2-point improvement from baseline on MG-ADL or 3-point improvement from baseline on QMG total scores)
- Proportion of patients achieving sustained MCI (≥2-point improvement on MG-ADL total score or 3-point improvement in QMG total score for ≥8 weeks) and minimal symptom expression (MSE; MG-ADL total score 0/1) at Week 24
- Safety: incidence of treatment-emergent adverse events (TEAEs) during the double-blind period

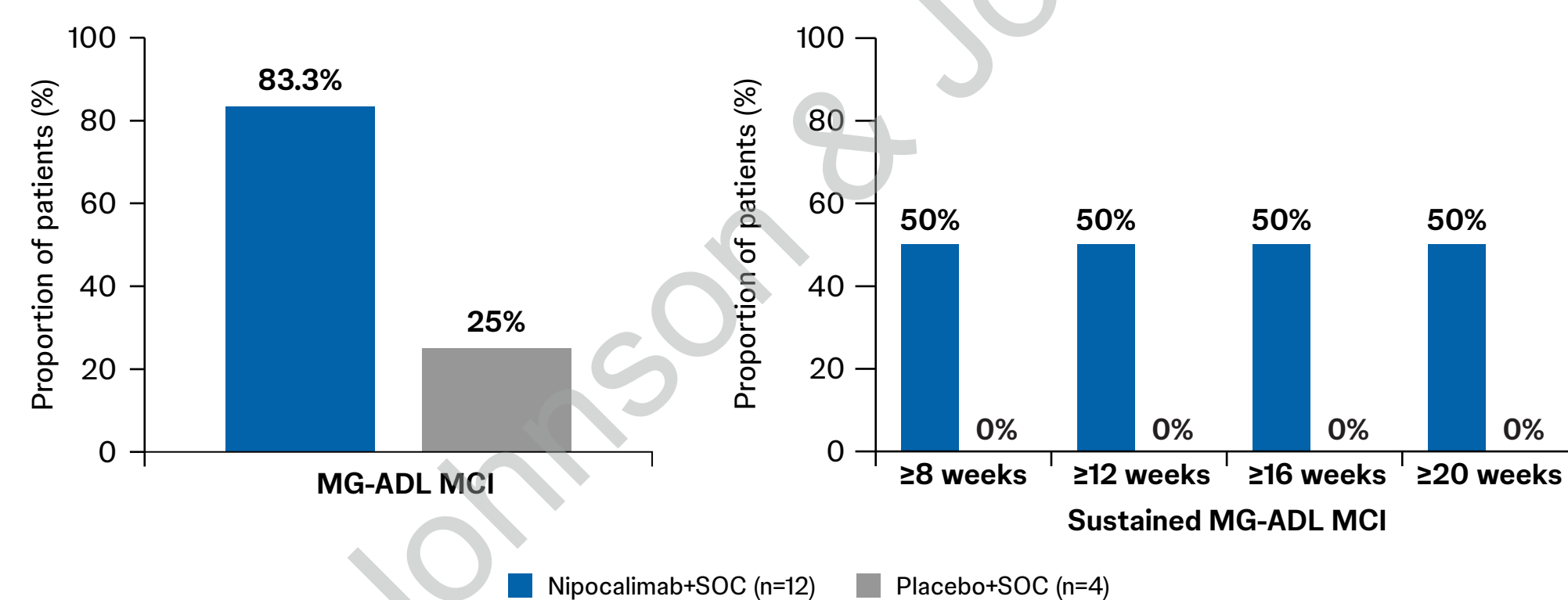
Statistical analysis

- Between-treatment group differences in LS mean changes from baseline were examined using an ANCOVA model with treatment group (nipocalimab, placebo) as a factor and baseline score as a covariate
- Differences between treatment groups for proportions of MCI and MSE were examined using odds ratios (ORs) and 95% confidence intervals (CIs)

MG-ADL total score: MCI and sustained MCI

- A greater proportion of patients receiving nipocalimab+SOC (vs placebo+SOC) achieved MG-ADL MCI at any time during the study: 10/12 (83.3%) vs 1/4 (25.0%) (Figure 3)
- Patients treated with nipocalimab+SOC (vs placebo+SOC) had greater odds of achieving MG-ADL MCI in the first 24 weeks
 - Unstratified odds ratio (OR) (95% CI): 15.00 (0.98; 228.89)
- Among the nipocalimab-treated patients, MG-ADL MCI was sustained for ≥8, ≥12, ≥16 and ≥20 weeks in 6/12 (50%) patients (vs 0/4 [0%] placebo-treated patients)

Figure 3. Proportion of patients achieving MG-ADL MCI^a at 24 weeks and sustained MCI^b (MuSK+ analysis set)

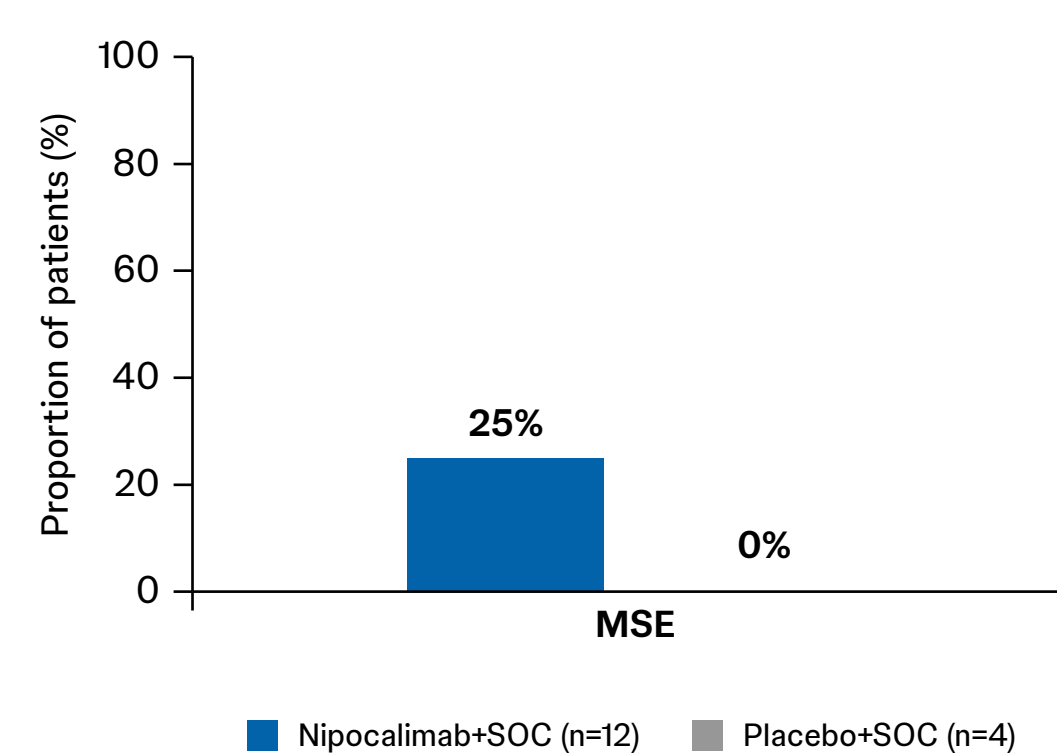


*MCI: defined as a ≥2-point improvement in MG-ADL total score from baseline. *Sustained MCI: defined as ≥2-point improvement in MG-ADL total score for ≥8 weeks. MCI=meaningful clinical improvement. MG-ADL=Myasthenia Gravis-Activities of Daily Living. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. SOC=standard-of-care.

MG-ADL total score: MSE

- A greater proportion of patients receiving nipocalimab+SOC (vs placebo+SOC) achieved MSE in the first 24 weeks: 3/12 (25%) vs 0% (Figure 4)

Figure 4. Proportion of patients achieving MG-ADL MSE^a at 24 weeks (MuSK+ analysis set)

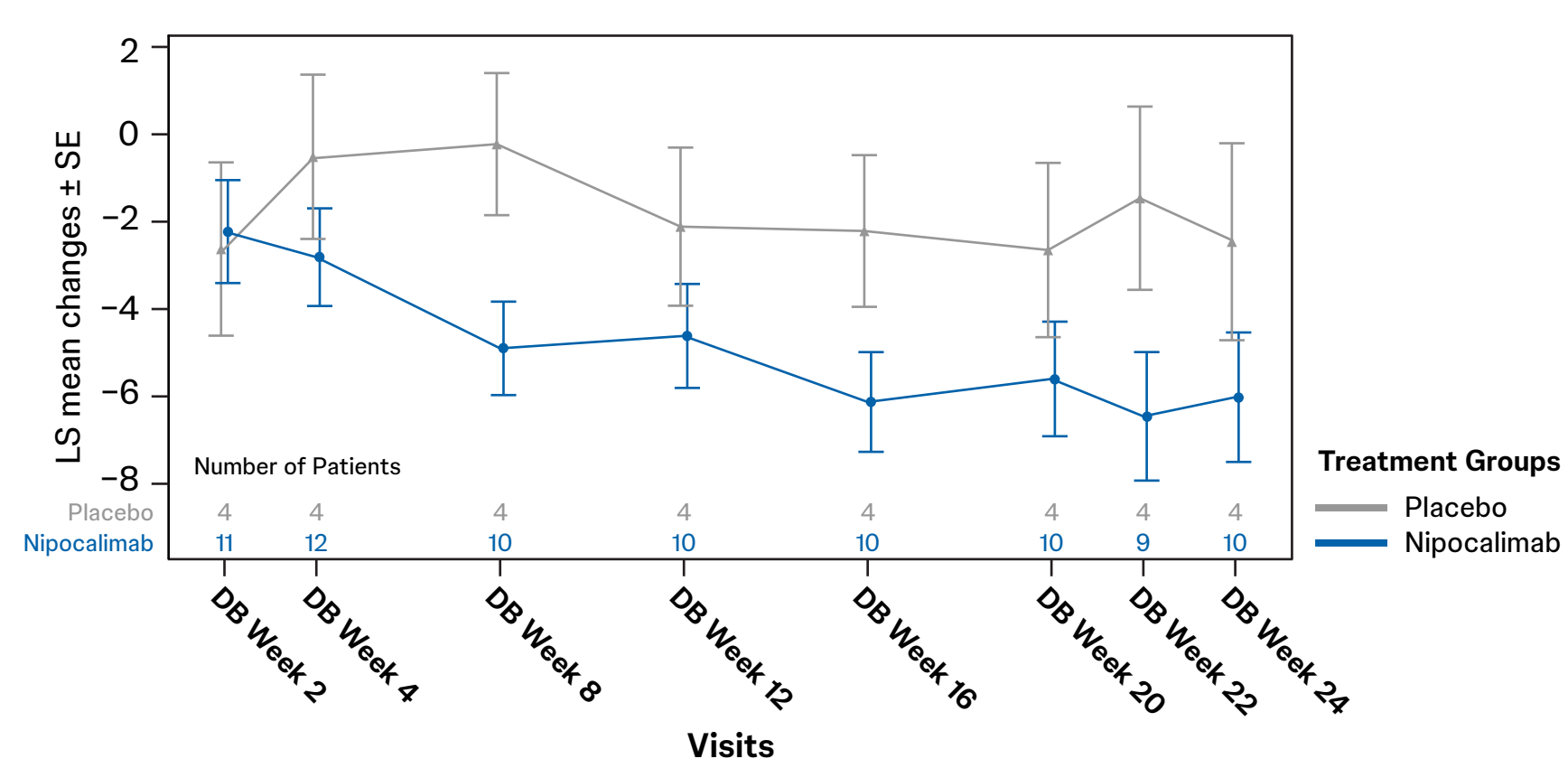


*MSE: defined as MG-ADL score of 0/1. MG-ADL=Myasthenia Gravis-Activities of Daily Living. MSE=minimal symptom expression. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. SOC=standard-of-care.

QMG total score: Change from baseline over time

- At Week 24, mean (SD) QMG total scores were: nipocalimab+SOC: 10.2 (7.18) vs placebo+SOC: 16.0 (6.06)
- Across the 24-week treatment period, patients receiving nipocalimab+SOC showed consistently greater reductions in QMG total scores compared with placebo+SOC (Figure 5)

Figure 5. LS mean change from baseline in QMG total score over time (MuSK+ analysis set)

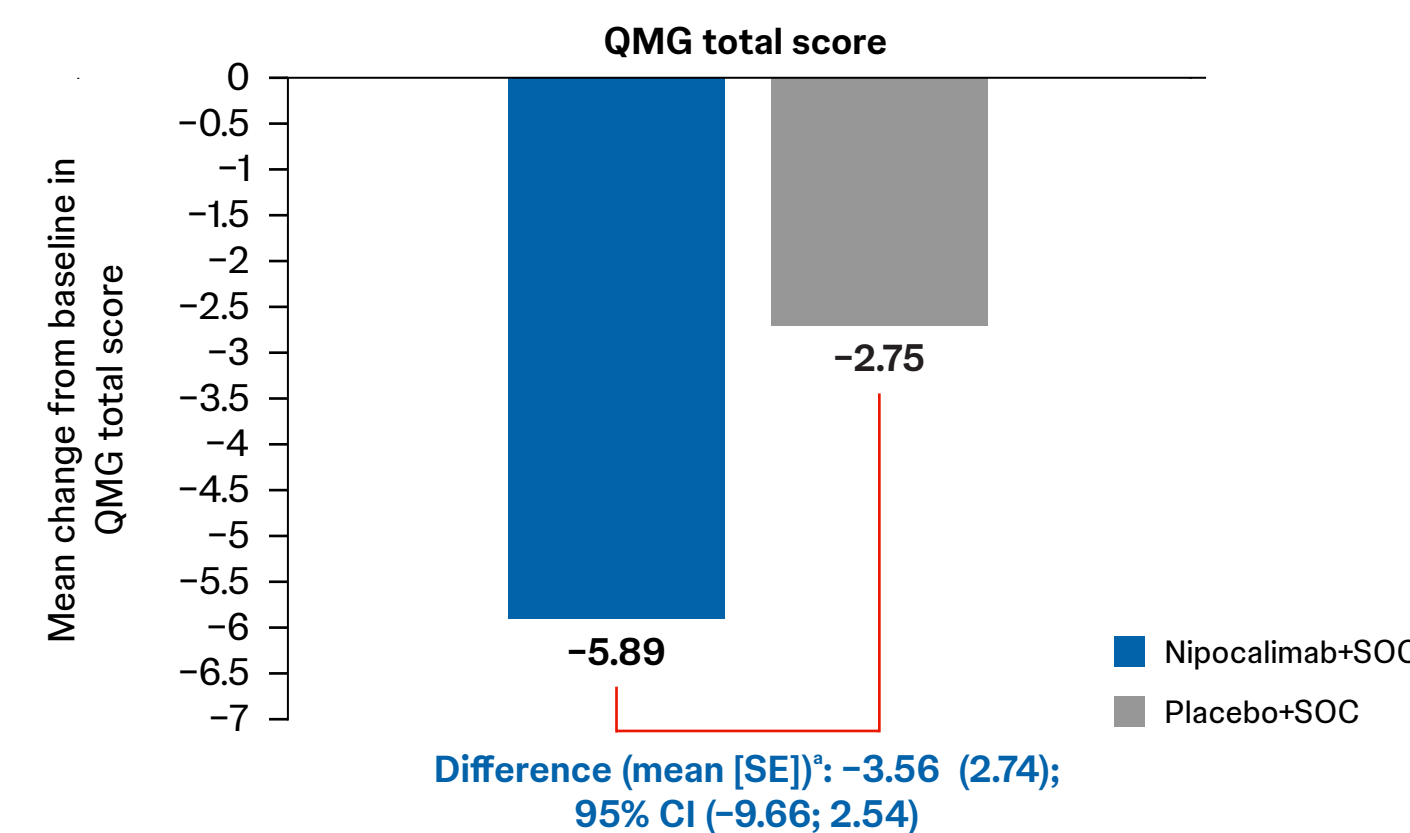


DB=double-blind, LS mean=least-squares mean, MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. QMG=Quantitative Myasthenia Gravis. SE=standard error, SOC=standard-of-care.

QMG total score: Mean change from baseline

- At Week 24, mean (SD) change from baseline in QMG total scores were: nipocalimab+SOC: -5.89 (4.75) vs placebo+SOC: -2.75 (2.53) (Figure 6)

Figure 6. Mean change from baseline to Week 24 in QMG total scores (MuSK+ analysis set)

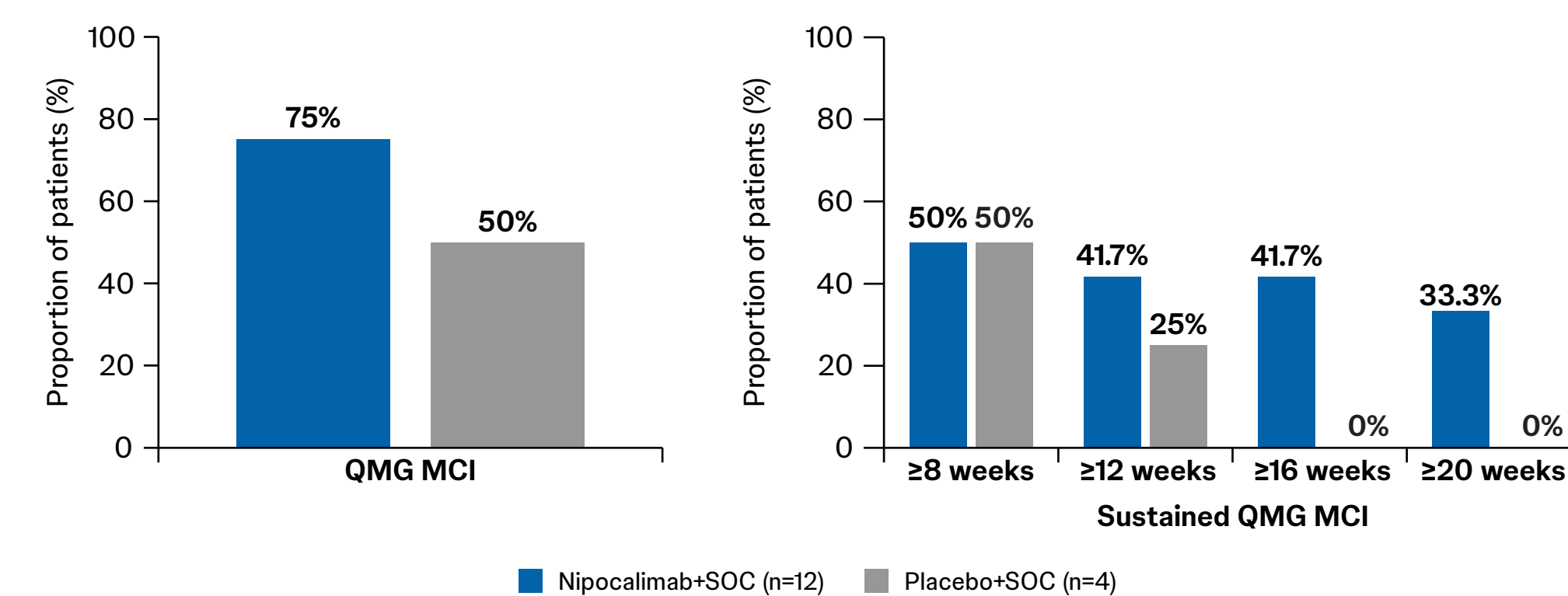


*Based on ANCOVA model with treatment group as factor and baseline QMG total score as the covariate. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. QMG=Quantitative Myasthenia Gravis. SE=standard error. SOC=standard-of-care.

QMG total score: MCI and sustained MCI

- A greater proportion of patients receiving nipocalimab+SOC (vs placebo+SOC) achieved QMG MCI at any time during the study: 9/12 (75.0%) vs 2/4 (50.0%) (Figure 7)
- Patients treated with nipocalimab+SOC (vs placebo+SOC) had greater odds of achieving QMG MCI in the first 24 weeks
 - Unstratified OR (95% CI): 3.00 (0.28; 31.63)
- Among patients achieving QMG MCI (nipocalimab+SOC vs placebo+SOC), MCI was sustained for:
 - ≥8 weeks in 6/12 (50.0%) (vs 2/4 [50.0%]) patients: unstratified OR (95% CI)=1.00 (0.10; 9.61)
 - ≥12 weeks in 5/12 (41.7%) (vs 1/4 [25.0%]) patients: unstratified OR (95% CI)=2.14 (0.17, 27.10)
 - ≥16 weeks in 5/12 (41.7%) (vs 0%), and ≥20 weeks in 4/12 (33.3%) (vs 0%) patients

Figure 7. Proportion of patients achieving QMG MCI^a at 24 weeks and sustained MCI^b (MuSK+ analysis set)



*MCI: defined as a ≥3-point improvement in QMG total score from baseline. *Sustained MCI: defined as ≥3-point improvement in QMG total score for ≥8 weeks. MCI=meaningful clinical improvement. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. QMG=Quantitative Myasthenia Gravis. SOC=standard-of-care.

Safety

- In the nipocalimab+SOC group, the mean duration of follow-up was 21.9 weeks (vs 24.1 weeks, placebo+SOC) and mean number of administrations was 10.3 (vs 12.0, placebo+SOC)
- TEAEs were reported in 8/12 (66.7%) patients in the nipocalimab+SOC group and 3/4 (75.0%) patients in the placebo+SOC group (Table 2)
- No deaths were reported and 1 patient experienced ≥1 serious adverse event

Table 2. Safety Summary (MuSK+ analysis set)

	Nipocalimab+SOC (n=12)	Placebo+SOC (n=4)
Any TEAE	8 (66.7)	3 (75.0)
Related TEAE ^a	4 (33.3)	2 (50.0)
TEAEs leading to death ^b	0	0
Any serious TEAEs	1 (8.3)	0
Related serious TEAEs	0	0
TEAE leading to temporary discontinuation of study drug ^c	2 (16.7)	0
TEAE leading to permanent discontinuation of study drug ^d	1 (8.3)	0
TEAEs leading to termination of study participation	1 (8.3)	0
COVID-19 associated TEAEs ^e	1 (8.3)	1 (25.0)
COVID-19 associated serious TEAEs ^e	0	0

All data are n (%). *A TEAE is assessed by the investigator as related to study agent. *TEAEs leading to death are based on TEAE outcome of fatal. *TEAEs leading to temporary discontinuation of study treatment is based on TEAE action taken of drug interrupted. *TEAEs leading to permanent discontinuation of study treatment is based on TEAE action taken of drug withdrawn. *COVID-19 associated TEAEs are based on events that code to a COVID-19 MedDRA term. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. SE=standard error. TEAE=treatment-emergent adverse event.

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