

Assessment of Health-Related Quality of Life Measures in Anti-Muscle-Specific Tyrosine Kinase Antibody-Positive Patients With Generalized Myasthenia Gravis: Post Hoc Analysis of the Vivacity-MG3 Study

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Introduction

- Anti-acetylcholine receptor (anti-AchR) autoantibody-mediated disease is the most prevalent (up to 85%) subtype of generalized myasthenia gravis (gMG); however, anti-muscle-specific tyrosine kinase (anti-MuSK) antibodies are causative in nearly 8% of patients and is linked to a more severe and refractory disease phenotype^{1,2}
- Severe bulbar, facial and respiratory symptoms in anti-MuSK-gMG are associated with rapid early disease progression, contributing to substantial functional impairment and poor health-related quality of life (HRQoL) in these patients^{2,3}
- Nipocalimab is the first approved neonatal Fc receptor blocker for the treatment of gMG across a broad population of adult and adolescent (≥12 years of age) patients who are anti-AChR or anti-MuSK antibody-positive^{4,5}
- Nipocalimab added to standard-of-care (SOC) (vs placebo+SOC) has demonstrated rapid and sustained clinical improvements on established MG rating scales as well as sustained improvements in fatigue and health-related QoL (HRQoL) over 24 weeks among seropositive patients with gMG in the phase 3 Vivacity-MG3 study⁶⁻⁸
- In this post hoc analysis we report improvements in HRQoL with nipocalimab+SOC in a subgroup of anti-MuSK antibody-positive patients with gMG

Objective

To evaluate changes in patient-reported HRQoL and fatigue among anti-MuSK antibody-positive patients with gMG in the Vivacity-MG3 study

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 analysis⁶	
Endpoints • Mean change from baseline to Week 24 and the proportion of patients achieving a meaningful within-patient change, defined as minimal clinical improvement (MCI) from baseline, as well as sustained MCI (≥8 weeks), were determined for each treatment group across the three patient-reported outcome instruments	
MG-QoL15⁹ • MG-specific HRQoL instrument used to measure disease-specific QoL in patients with MG over the past few weeks • Total score ranges from 0 to 30 • Higher scores indicate a more severe condition and negative change in score indicates improvement • MCI was defined as: ≥4-point improvement	EQ-5D-VAS¹⁰ • Measure of overall health on a vertical VAS ranging from 0 (worst health you can imagine) to 100 (best health you can imagine) • Higher scores indicate favorable HRQoL and positive change in score indicates improvement • MCI was defined as: ≥10-point improvement
Neuro-QoL Fatigue¹¹ • A PRO measure of general fatigue and associated impacts over the past seven days in adult patients with gMG • Scores are reported as a standardized T-score (with a mean of 50 and standard deviation of 10) • Higher scores indicate a more severe condition and negative change in score indicates improvement • MCI was defined as: ≥6.7-point improvement	

EQ-5D VAS=European Quality of Life Group, 5 Dimension Visual Analog Scale. MG-QoL15=15-item Myasthenia Gravis Quality of Life (revised) instrument. Neuro-QoL Fatigue=Quality of Life in Neurological Disorders Fatigue scale.

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 were examined using odds ratios (ORs) and 95% confidence intervals (CIs)	
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Results

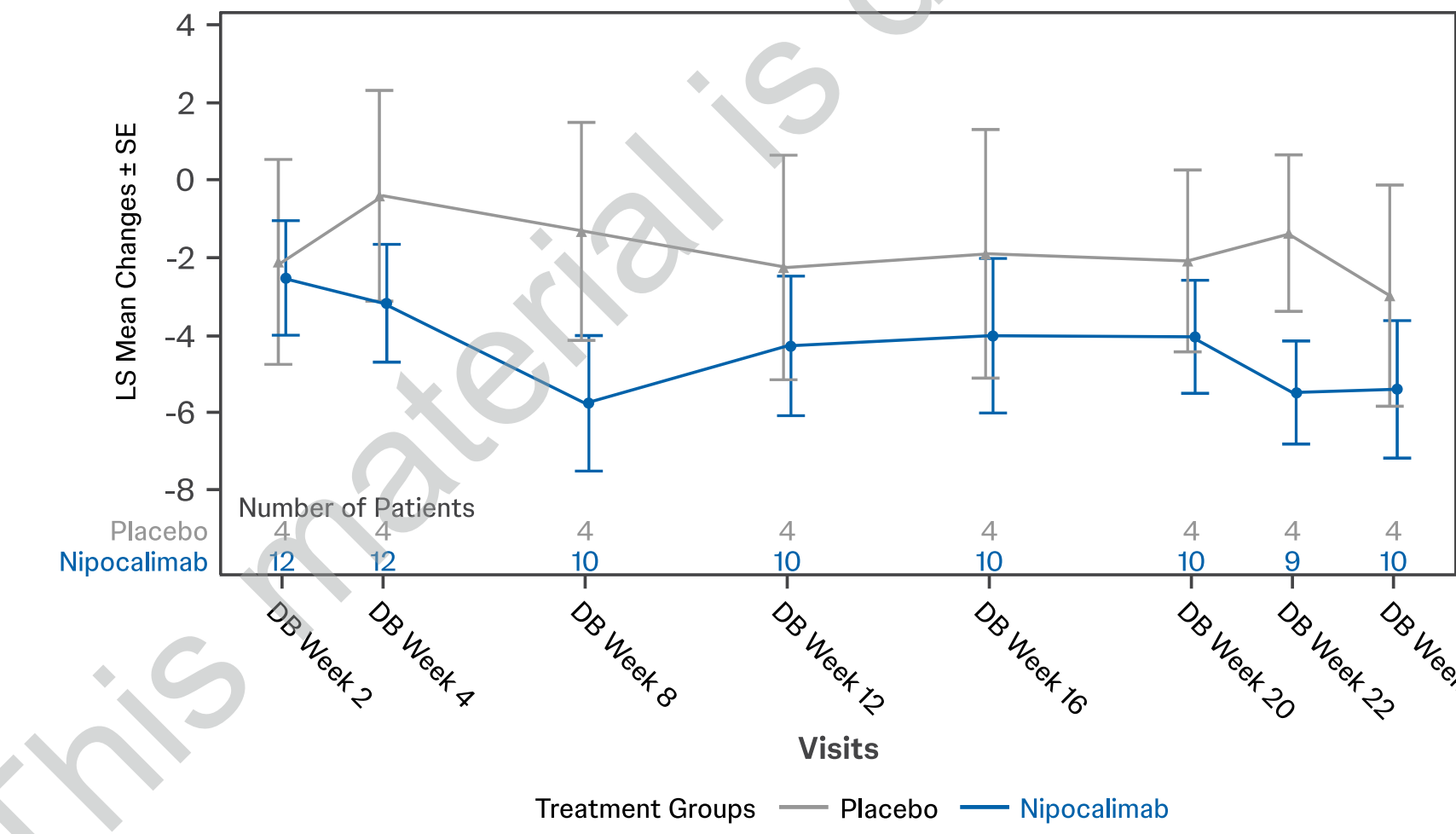
Baseline demographics	
• A total of 16 patients (nipocalimab+SOC: n=12; placebo+SOC: n=4) were anti-MuSK antibody-positive • Patients in the nipocalimab+SOC group (vs placebo+SOC) were older, and the majority of patients in both groups were females (Table 1) • Mean baseline MG-QoL15r and EQ-5D-VAS scores were generally comparable between the treatment groups, while the Neuro-QoL Fatigue scores were higher in the nipocalimab+SOC group	

	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)
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 (25–33)
Baseline MG-QoL15r total score, mean (SD)	18.5 (7.53)	13.0 (3.37)
Baseline EQ-5D-VAS score, mean (SD)	56.5 (19.28)	55.3 (27.96)
Baseline Neuro-QoL Fatigue total score, mean (SD)	64.0 (18.19)	46.8 (10.63)
Antibody-positive at screening, n (%)		
Seropositive- Anti-MuSK+	12 (100.0)	4 (100.0)

Note: Please refer to Poster #433 for additional data on the anti-MuSK antibody-positive subgroup. *nipocalimab+SOC, n=11. EQ-5D VAS=European Quality of Life Group, 5 Dimension Visual Analog Scale. MG=myasthenia gravis. MG-QoL15r=Myasthenia Gravis Quality of Life (revised) instrument. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive. Neuro-QoL Fatigue=Quality of Life in Neurological Disorders Fatigue scale. SD=standard deviation. SOC=standard-of-care.

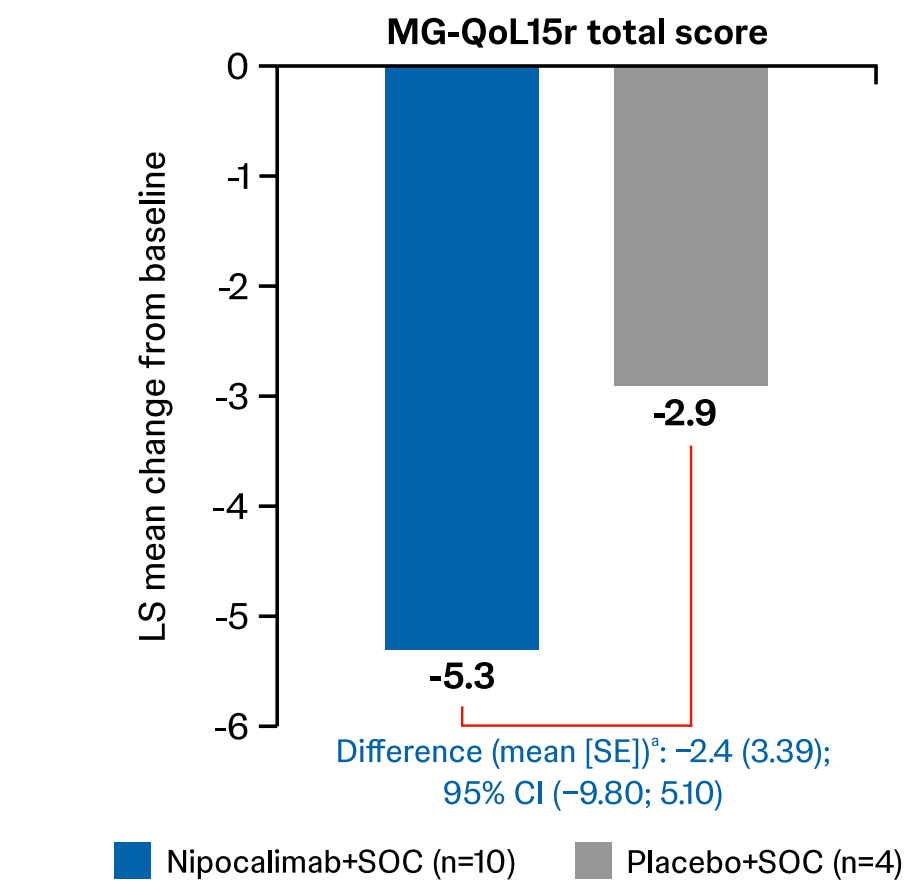
MG-QoL15r: LS mean change from baseline and MCI	
• LS-mean (95% CI) difference in change from baseline in nipocalimab+SOC-treated patients versus placebo+SOC-treated patients at Week 2 was –0.4 (–7.00; 6.20) and –2.4 (–9.80; 5.10) at Week 24, both in favor of nipocalimab+SOC (Figure 1, 2) • At Week 24, a greater proportion of patients receiving nipocalimab+SOC (vs placebo+SOC) achieved MCI on MG-QoL15r (60% vs 0%) (Figure 3) • Among nipocalimab-treated patients, MG-QoL15r MCI was sustained for ≥8, ≥12, ≥16 and ≥20 weeks in 2/12 (16.7%) patients (vs 0% in placebo-treated patients)	

Figure 1. LS mean change from baseline to Week 24 in MG-QoL15r total score (MuSK+ analysis set)



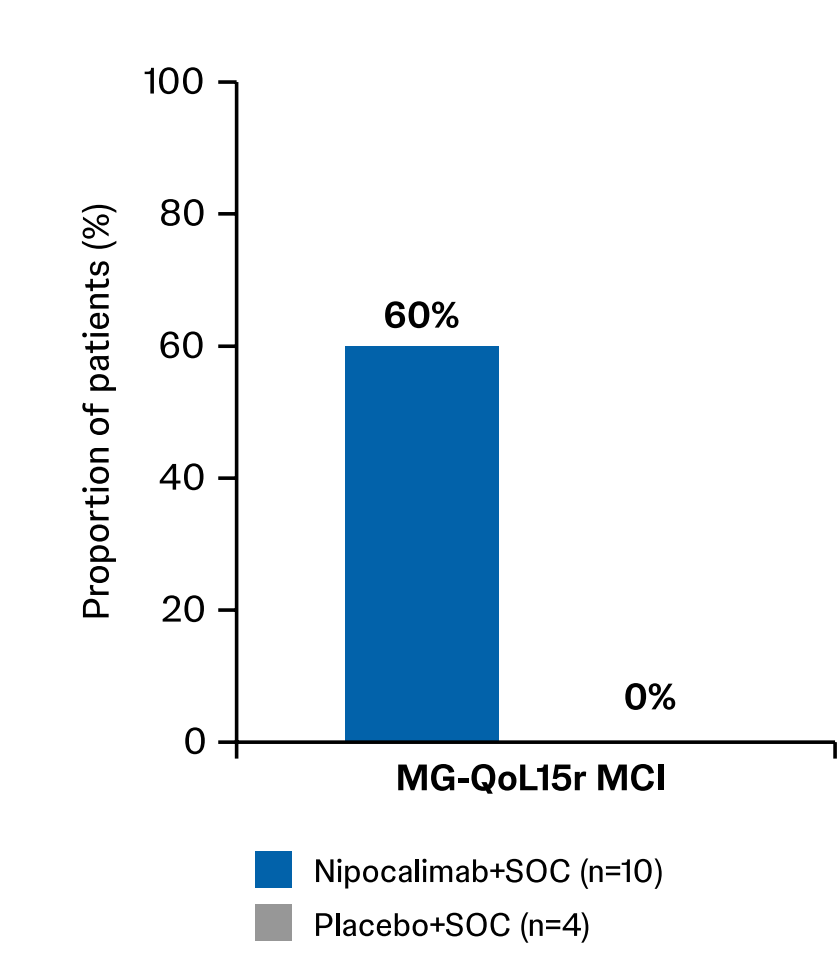
DB=double blind, LS=least square, MG-QoL15r=Myasthenia Gravis Quality of Life (revised) instrument, MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, SE=standard error, SOC=standard-of-care

Figure 2. LS mean change from baseline to Week 24 in MG-QoL15r total score (MuSK+ analysis set)



*Based on ANCOVA model with treatment group as factor and baseline MG-QoL15r total score as the covariate. LS=least square, MG-QoL15r=Myasthenia Gravis Quality of Life (revised) instrument. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, SE=standard error, SOC=standard-of-care.

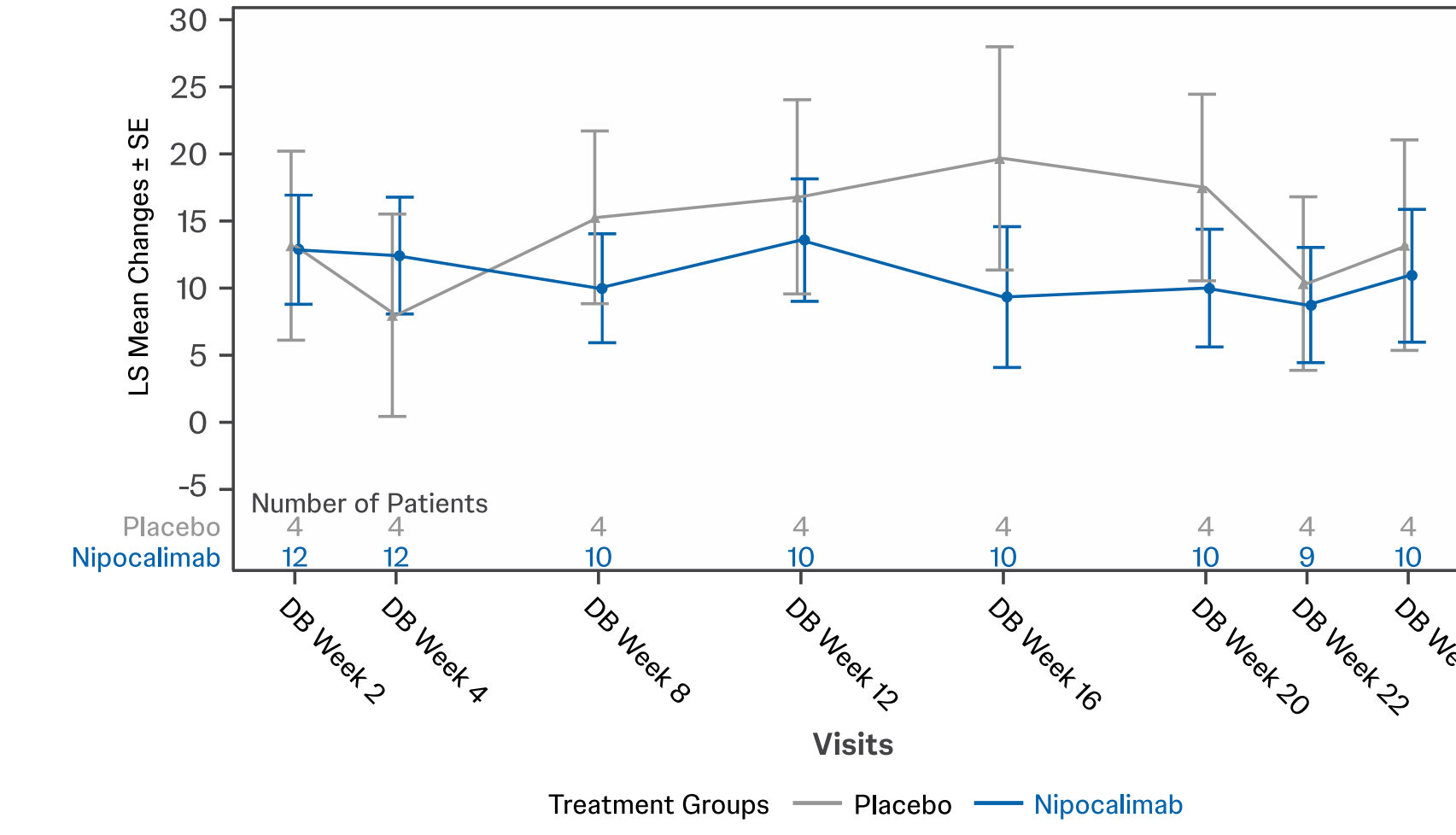
Figure 3. Proportion of patients achieving MCI on MG-QoL15r at Week 24 (MuSK+ analysis set)



MG-QoL15r=Myasthenia Gravis Quality of Life (revised) instrument, MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, SE=standard error, SOC=standard-of-care.

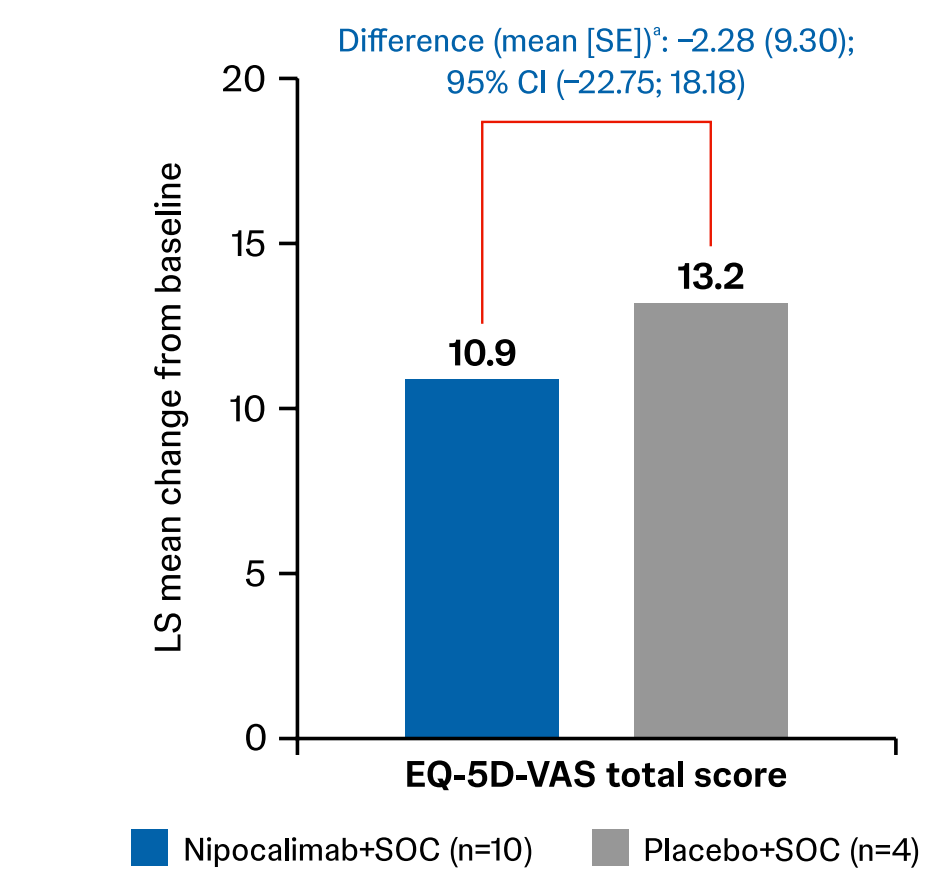
EQ-5D-VAS: LS mean change from baseline and MCI	
• LS-mean (95% CI) difference in change from baseline in nipocalimab+SOC-treated patients versus placebo+SOC-treated patients at Week 2 was –0.3 (–17.87; 17.27) and –2.28 (–22.75; 18.18) at Week 24, both in favor of placebo+SOC (Figure 4, 5) • At Week 24, a greater proportion of patients on placebo+SOC (vs nipocalimab+SOC) achieved MCI on EQ-5D-VAS (Figure 6) • Among nipocalimab-treated patients, EQ-5D-VAS MCI was sustained for ≥8 weeks in 4/12 (33.3%) patients, for ≥12 weeks in 3/12 (25%) patients and for ≥16 and ≥20 weeks in 2/12 (16.7%) patients (vs 2/4 [50.0%] in placebo-treated patients at all timepoints)	

Figure 4. LS Mean change on EQ-5D-VAS from baseline over time (MuSK+ analysis set)



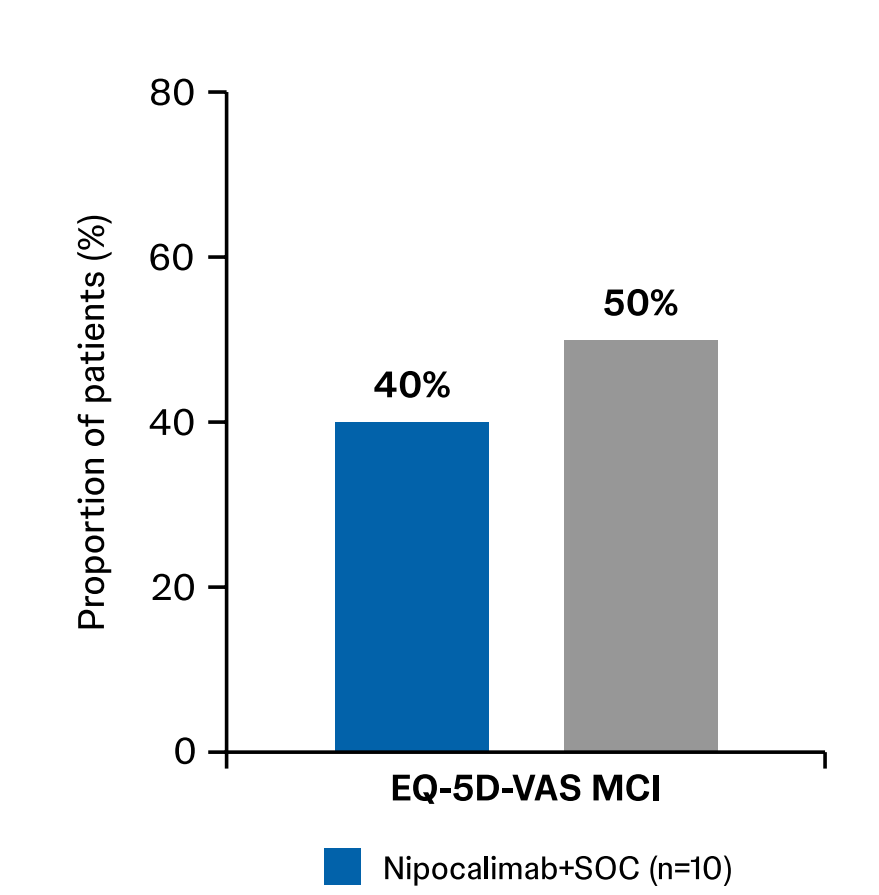
DB=double blind, EQ-5D VAS=European Quality of Life Group, 5 Dimension Visual Analog Scale. LS=least square, MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, SE=standard error, SOC=standard-of-care.

Figure 5. LS mean change from baseline to Week 24 in EQ-5D-VAS total score (MuSK+ analysis set)



*Based on ANCOVA model with treatment group as factor and baseline EQ-5D-VAS score as the covariate. EQ-5D VAS=European Quality of Life Group, 5 Dimension Visual Analog Scale. LS=least square, MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, SE=standard error, SOC=standard-of-care.

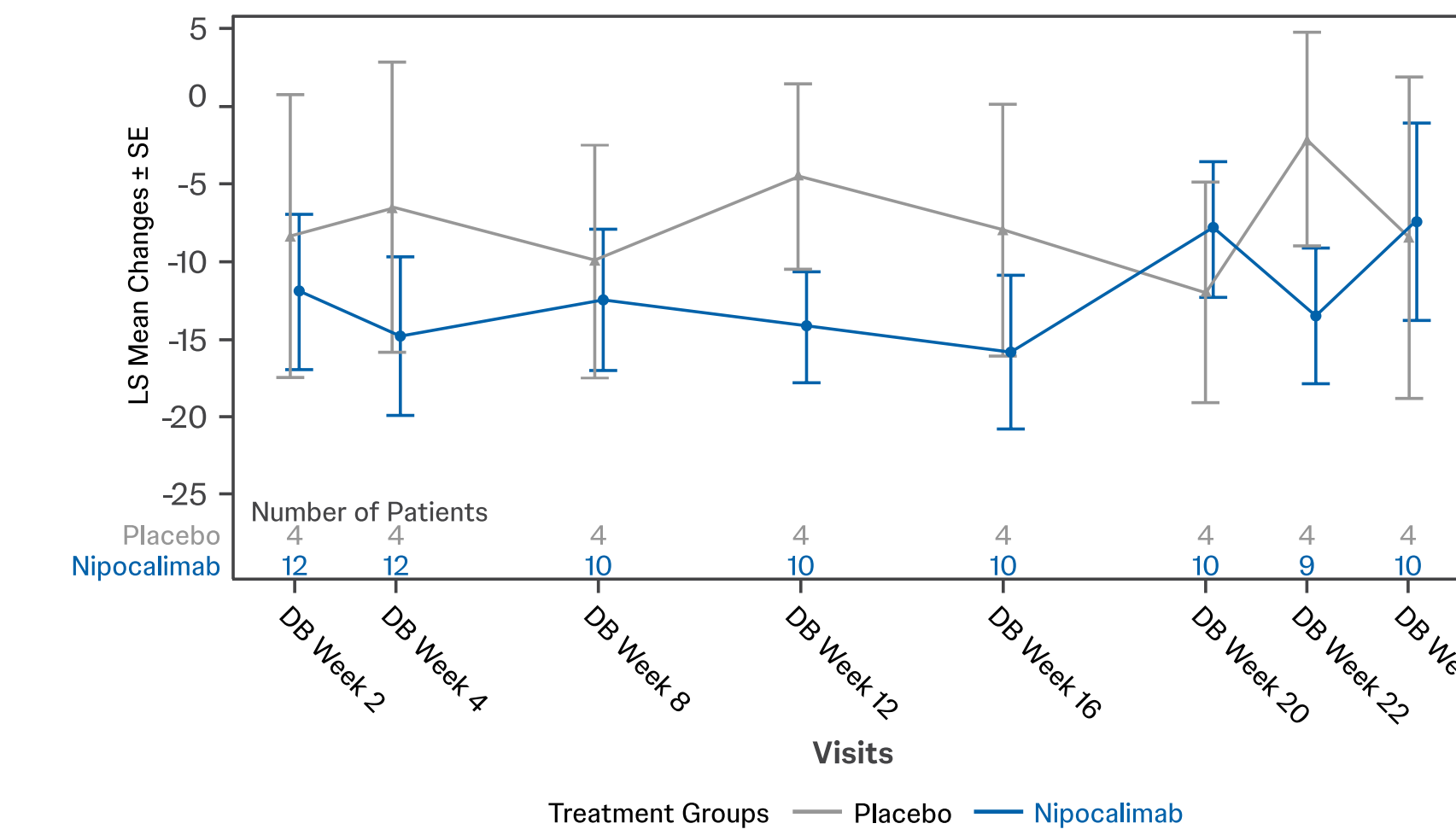
Figure 6. Proportion of patients achieving MCI on EQ-5D-VAS at Week 24 (MuSK+ analysis set)



EQ-5D VAS=European Quality of Life Group, 5 Dimension Visual Analog Scale. MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, SE=standard error, SOC=standard-of-care.

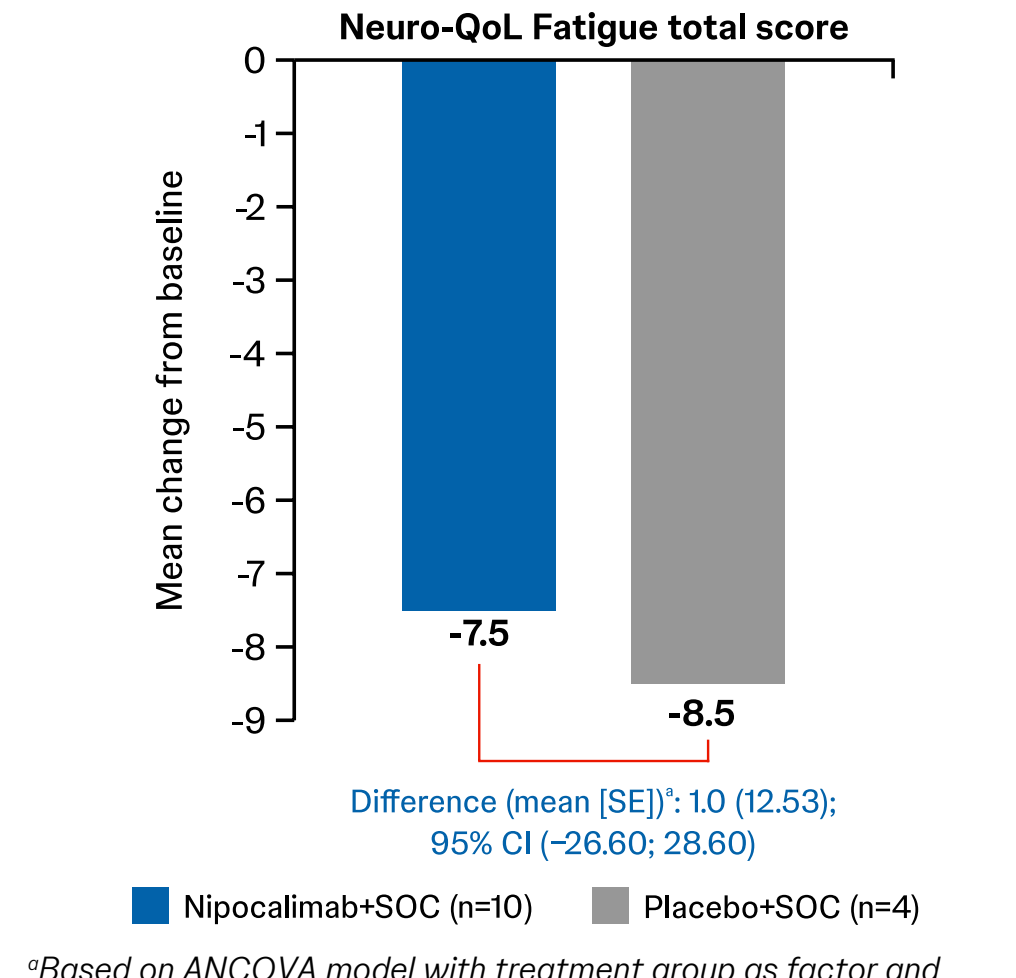
Neuro-QoL Fatigue: LS mean change from baseline and MCI	
• LS-mean (95% CI) difference in change from baseline in nipocalimab+SOC-treated patients versus placebo+SOC-treated patients at Week 2 was –3.5 (–26.60; 19.60), in favor of nipocalimab+SOC and 1.0 (–26.60; 28.60) at Week 24, in favor of placebo+SOC (Figure 7, 8) • At Week 24, a greater proportion of patients receiving nipocalimab+SOC (vs placebo+SOC) achieved MCI on Neuro-QoL Fatigue (60% vs 0%) (Figure 9) • Among nipocalimab-treated patients, Neuro-QoL Fatigue MCI was sustained for ≥8 and 12 weeks in 6/12 (50.0%) patients, for ≥16 and 20 weeks in 4/12 (33.3%) patients (vs 0% in placebo-treated patients at all timepoints)	

Figure 7. LS Mean change on Neuro-QoL Fatigue total score from baseline over time (MuSK+ analysis set)



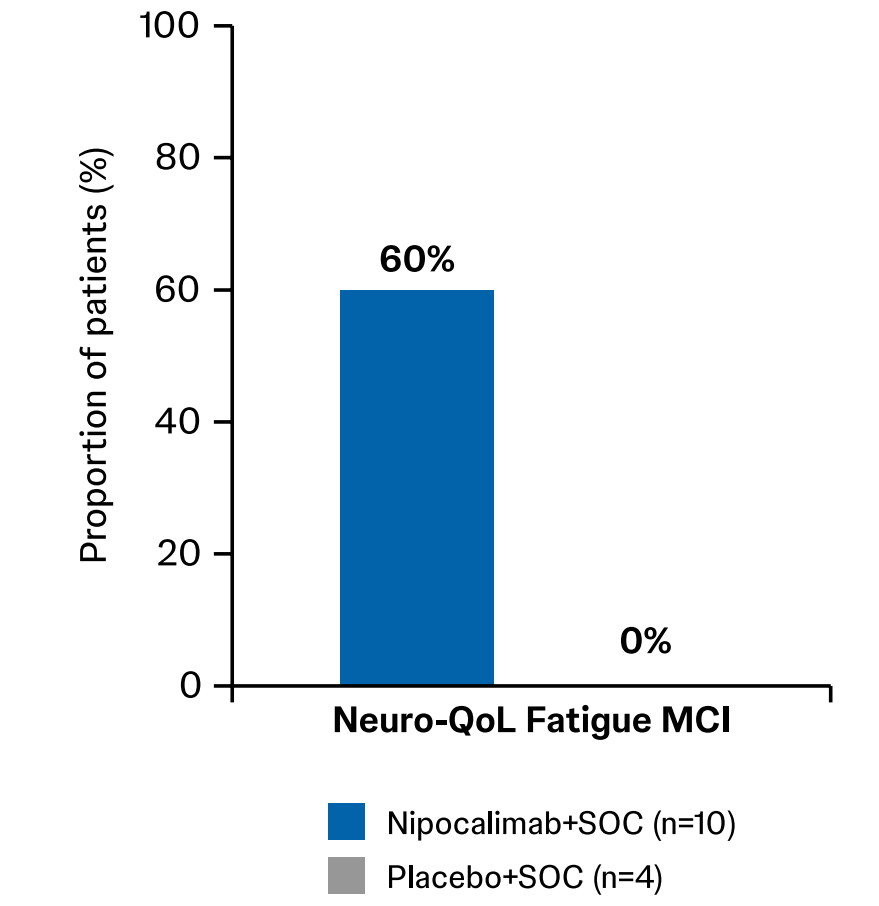
DB=double blind, LS=least square, MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, Neuro-QoL Fatigue=Quality of Life in Neurological Disorders Fatigue scale, SE=standard error, SOC=standard-of-care.

Figure 8. LS mean change from baseline to Week 24 in Neuro-QoL Fatigue total score (MuSK+ analysis set)



*Based on ANCOVA model with treatment group as factor and baseline Neuro-QoL Fatigue total score as the covariate. LS=least square, MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, SE=standard error, SOC=standard-of-care.

Figure 9. Proportion of patients achieving MCI on Neuro-QoL Fatigue at Week 24 (MuSK+ analysis set)



MuSK+=anti-muscle-specific tyrosine kinase antibody-positive, Neuro-QoL Fatigue=Quality of Life in Neurological Disorders Fatigue scale, SE=standard error, SOC=standard-of-care.

PRESENTED AT: The American Association of Neuromuscular & Electrophysiology Medicine (AANEM) Annual Meeting, September 29–October 2, 2026; Orlando, FL, USA. REFERENCES: 1. Vakkou AG, et al. *Front Immunol*. 2023;14:121257. 2. Gupta JJ, et al. *Muscle Nerve*. 2010;44(1):36–40. 3. Stankovic M, et al. *Acta Neurol Belg*. 2016;118(3):423–427. 4. IMAGVY™ (nipocalimab-sau) injection for intravenous use [Package insert] Horsham, PA: Janssen Pharmaceutical Companies, August 2026. 5. European Medicines Agency (EMA). European Medicines Agency. 2025 Sep 22. <https://www.ema.europa.eu/en/medicines/human/EPAR/nipocalimab>. 6. Antozzi G, et al. *Lancet Neurol*. 2025;24(2):105–118. 7. Viti T, et al. *Eur J Neurol*. 2026;33(6):10590. 8. Weising J, et al. *J Neurol*. 2026;273(7):123. 9. Burns TM, et al. *Muscle Nerve*. 2016;54:1015–22. 10. Fang YS, et al. *Qual Life Res*. 2024;33:641–673. 11. Rabon A, et al. *Qual Life Res*. 2017;26(7):2659. ACKNOWLEDGMENTS: Medical writing support was provided by Priya Gangpathy, MPH, CLPP (SIRIO Clingham UK Ltd.) and Doyel Mitra, PhD (Johnson & Johnson) provided additional editorial support. Graphic designing support was provided by Ganesh Karpe (SIRIO Medical Writing Pvt. Ltd., India). DISCLOSURES: Rosemarie Walch: consultants for Alexion, Bristol Myers Squibb, Genentech/Roche, Horizon/Angen, argenx, TG Therapeutics, Johnson & Johnson, and Sanofi; speakers bureau for Alexion, Bogen, Bristol Myers Squibb, EMD Serono, Horizon/Angen, TG Therapeutics, argenx, and Johnson & Johnson; and institutional research support from EMD Serono, Genentech/Roche, Novartis, Sanofi, and TG Therapeutics. Mazen Dimachkie: received consultancy fees, payment or honoraria for lectures, presentations, manuscript writing or educational events, or participated on a Data Safety Monitoring Board or Advisory Board for AAN, AANEM, Aburo, Amicus, Amnexus, argenx, Astellas, Astra Zeneca, Cabaletta Bio, Candor Therapeutics, Catalyt, Covance/Labcorp/Forrea, CSL-Behring, Croyon Bio, Inc, Dianthus, EMD Serono/Merck, Horizon, Ig Society, Inc, Janssen, Krka Therapeutics, Inc, Medlink, Nuvo, Octapharma, Sanofi Genzyme, Shire Takeda, and TACIT/Treat NMD, UCB and Vertex; has received grants from Aburo, Alexion/ AstraZeneca, Amylan Pharmaceuticals, Amicus, argenx, Biosciences, Bristol-Myers Squibb, Cabaletta Bio, Catalyst, CSL-Behring, EMD Serono, FDA/OOPD, GlaxoSmithKline, Genentech, Grifols, Horizon Immunovant, Mitsubishi Tanabe Pharma, MDA, NIH, Nkarta, Novartis, Octapharma, Orphazyme, Provant, Ra Pharma/UCB Biopharma, Sanofi Genzyme, Sarepta Therapeutics, Shire Takeda, Spark Therapeutics, and The Myasthenia Association; received royalty for manuscript writing from Wolters Kluwer Health/UpToDate and from Elsevier and for discovery relating to health care from Zevra Therapeutics. Marie Fitzgibbon, Carly Paoli, Sheryl Pease, Ibrahim Turkoz, Sindhu Ramchandren: Employees of Johnson & Johnson and may hold stock or stock options in Johnson & Johnson. Nolan Campbell: Former employee of Johnson & Johnson and presently is an employee of Vor Bio. Nolan owns stock in Johnson & Johnson and Vor Bio. FUNDING: This study was funded by Johnson & Johnson.