Assessment of Patient-Reported Outcomes from the Phase 3 Vivacity-MG3 Study of Nipocalimab in Generalized Myasthenia Gravis

Elena Cortés Vicente,[1] Sheryl Pease,[2*] Nida Imran,[2] Kavita Gandhi,[2] Maria Ait-Tihyaty,[2¥] Ibrahim Turkoz,[3] Geoffroy Coteur,[2,4] Charlotte Gary,[5] Zia Choudhry,[3] Sindhu Ramchandran,[3] John Vissing[6]
[1]Unitat Patologia Neuromuscular, Servei Neurologia, Hospital Santa Creu i Sant Pau, Barcelona; [2]Johnson & Johnson, Raritan, NJ, USA; [3]Johnson & Johnson, Horsham, PA, USA;
[4]IPATH Solutions, Wemmel, Belgium; [5]Johnson & Johnson, Issy-les-Moulineaux, France; [6]Department of Neurology, University of Copenhagen, Copenhagen, Denmark

*Presenting author
¥Affiliation at the time of study

Key Takeaways

- **Nipocalimab-treated patients reported significantly greater improvements in patient-reported health status and numerically greater treatment satisfaction compared with placebo-treated patients.**
  - **Nipocalimab + SOC-treated patients reported significantly greater improvements as early as Week 2 vs placebo + SOC on health status, as assessed by EQ-5D-5L VAS, and these improvements were sustained over the 24-week period.**
  - **Numerically greater satisfaction scores were observed with nipocalimab than with placebo on patient-reported global measures and treatment satisfaction, as measured by TSQM-9 at 24 weeks.**

Background

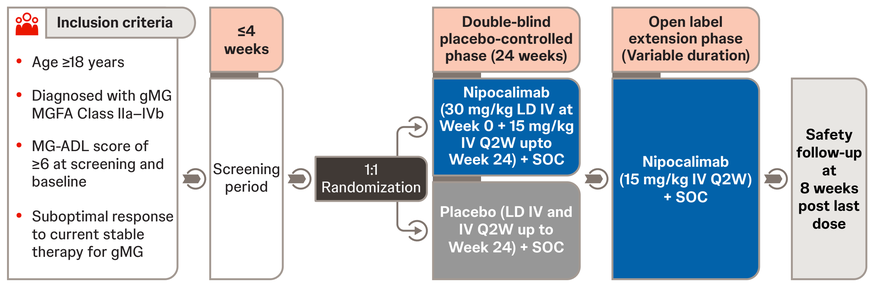
- Generalized myasthenia gravis (gMG) is a rare, chronic, immunoglobulin G (IgG)-mediated autoimmune disease that causes fluctuating and potentially life-threatening muscle weakness.[1,2]
- It significantly impacts multiple domains of patient health, with greater disease severity linked to poorer health-related quality of life (HRQoL).[3]
- Many patients experience substantial residual disease burden and poor HRQoL even when gMG appears clinically controlled.[4,5]
- As severity and distribution of muscle function impacts vary among patients, accurate assessment of overall disease burden and treatment effects also entails impacts on HRQoL and treatment satisfaction.[6]
- Nipocalimab as an add-on therapy to standard-of-care (SOC) has demonstrated statistically significant sustained and meaningful improvements versus placebo + SOC in a 24-week phase 3, randomized double-blind Vivacity-MG3 study in adults with gMG.[7]

Objective

- **To evaluate patient-reported HRQoL and treatment satisfaction among patients treated with nipocalimab + SOC vs placebo + SOC in Vivacity-MG3.**

Methods

Figure 1: Vivacity-MG3 study design



gMG=Generalized myasthenia gravis, **IV**=Intravenous, **LD**=Loading dose, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MGFA**=Myasthenia Gravis Foundation of America, **Q2W**=Every-2-weeks, **SOC**=Standard of care.

- The efficacy population included participants who were antibody-positive for a gMG-related pathogenic antibody (anti-acetylcholine receptor, anti-muscle-specific tyrosine kinase, or anti-low density lipoprotein receptor-related protein 4).
- HRQoL was assessed utilizing patient-reported outcomes (PRO) measures (**Table 1**) completed at varying timepoints throughout the double-blind phase of the study (**Figure 1**).
- Descriptive statistics were used to report and compare changes in PROs between treatment arms from baseline through Week 24.

Table 1: PRO measures used for HRQoL assessment

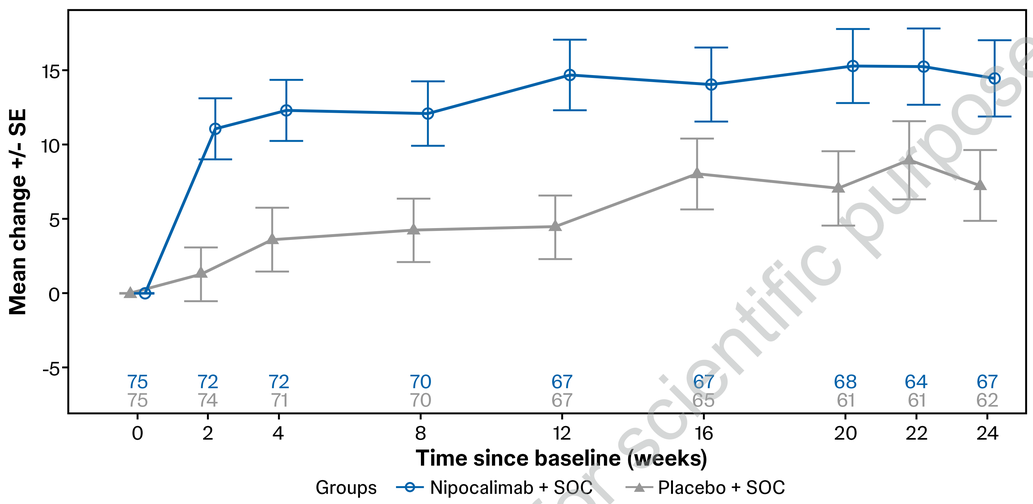
PRO Measure	Scoring Range	Interpretation
EQ-5D-5L VAS[a]	0–100	Higher scores indicate better health
PGIS[b]-Fatigue	1 (none)–5 (very severe)	Higher scores indicate more severe fatigue
PGIC[c]-Fatigue	1 (much better)–7 (much worse)	Higher scores indicate increased fatigue from baseline
TSQM-9[d]	0–100	Higher scores indicate greater satisfaction

[a]EQ-VAS self-rating records the respondent's own assessment of his or her overall health status. [b]Assesses fatigue severity. [c]Assesses change in fatigue severity. [d]9-item scale assessing effectiveness, convenience, and global satisfaction with treatment in the last 2–3 weeks. **EQ-5D-5L-VAS**=European Quality of Life Group, 5 Dimension, 5 Level version, Visual Analoug Scale, **HRQoL**=Health-realated quality of life, **PGIC**=Patient Global Impression of Change, **PGIS**=Patient Global Impression of Severity, **PRO**=Patient-reported outcomes, **TSQM**=Treatment Satisfaction Questionnaire for Medication.

Results

- By Week 2, patients receiving nipocalimab + SOC demonstrated a statistically significant improvement in European Quality of Life 5-Dimension, 5-Level version, Visual Analogue Scale (EQ-5D-5L-VAS) scores when compared with placebo + SOC (Least square mean difference: 8.1 [95% CI: 3.86, 12.30]; p<0.001).
  - Mean (95% Confidence interval [CI]) change from baseline (**Figure 2**): nipocalimab + SOC: 11.1 (7.1, 15.2); placebo + SOC: 1.3 (–2.2, 4.8).
- Nipocalimab-treated patient experienced sustained improvements in perceived health status through Week 24.
- At Week 24, the mean change (standard error [SE]) in EQ-5D-5L VAS score from baseline was 14.6 (2.56) in the nipocalimab + SOC arm and 7.3 (2.39) in the placebo + SOC arm, representing a 7.3-point higher mean change in the nipocalimab + SOC arm.

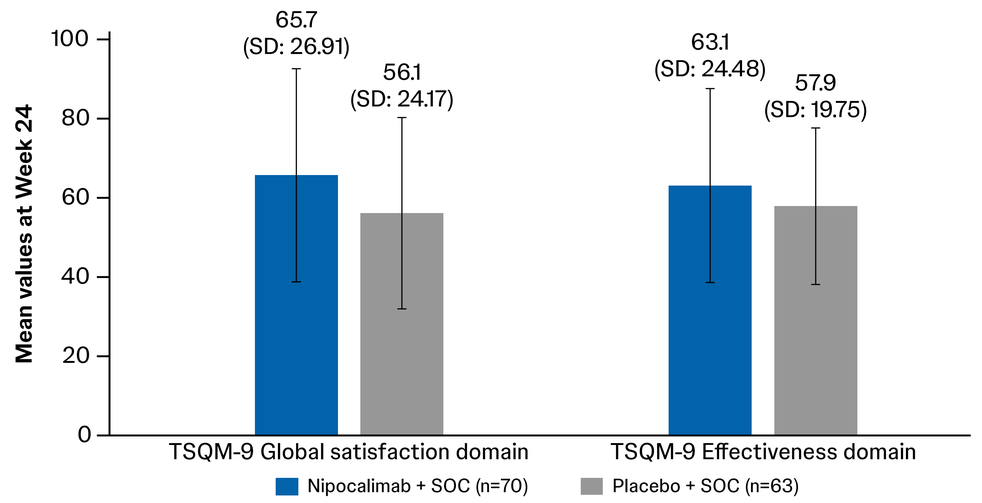
Figure 2: Mean change in EQ-5D-5L VAS scores across 24 weeks



EQ-5D-5L-VAS score range is 0–100. Positive score changes indicate improvement. **EQ-5D-5L-VAS**=European Quality of Life Group, 5 Dimension, 5 Level version, Visual Analoug Scale; **SE**=Standard error; **SOC**=Standard of care.

- At Week 24, the Global Satisfaction scores from the Treatment Satisfaction Questionnaire for Medication (TSQM-9) were numerically higher in the nipocalimab + SOC arm vs placebo + SOC arm (**Figure 4**).
  - Global Satisfaction scores were higher with nipocalimab + SOC (65.7 [standard deviation, SD 26.91]) vs placebo + SOC (56.1 [SD 24.17]), showing a 9.6-point difference favoring nipocalimab.
  - Effectiveness scores were also higher with nipocalimab + SOC (63.1 [SD 24.48]) vs placebo + SOC (57.9 [SD 19.75]), reflecting a 5.2-point difference favoring nipoclaimab.

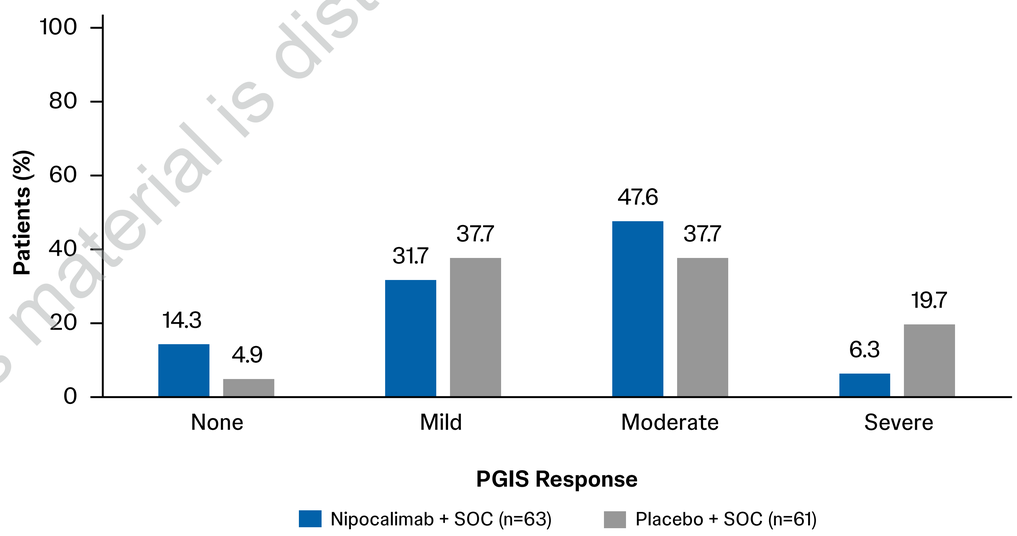
Figure 4: PRO scores per TSQM-9 scale at Week 24

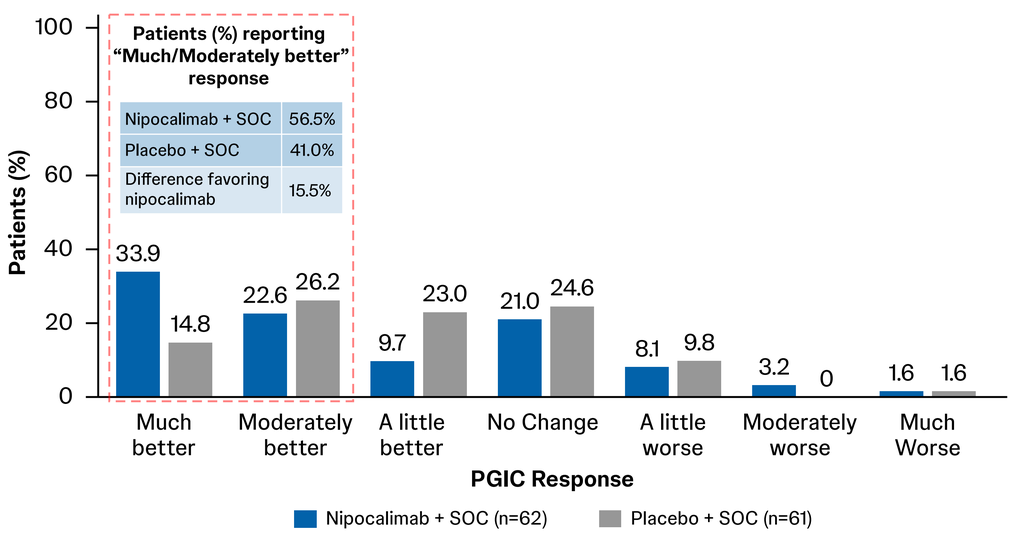


TSQM-9: 'Global satisfaction' and 'Effectiveness' domains each consists of 3 items. **PRO**=Patient-reported outcomes; **SD**=Standard deviation; **SOC**=Standard-of-care; **TSQM-9**=Treatment Satisfaction Questionnaire for Medication-9 items.

- At Week 24, a greater proportion of patients in the nipocalimab + SOC arm reported lower fatigue severity, with 14.3% reporting "None" compared to 4.9% in the placebo + SOC arm (**Figure 3**).
  - Conversely, fewer patients in the nipocalimab + SOC arm vs the placebo + SOC arm rated fatigue as "Severe" (6.3% vs 19.7%) on the Patient Global Impression of Severity (PGIS) at Week 24.
- 56.5% of patients in the nipocalimab + SOC arm reported fatigue as "much better" or "moderately better", which is 15.5% higher than the placebo + SOC arm (**Figure 3**).

Figure 3: PRO scores per PGIS[a]/PGIC at Week 24





[a]None of the patients reported PGIS response as "Very Severe". **PGIC**=Patient Global Impression of Change; **PGIS**=Patient Global Impression of Severity; **PRO**=Patient-reported outcomes; **SOC**=Standard-of-care.

PRESENTED AT: Myasthenia Gravis Foundation of America (MGFA) Scientific Session at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting; San Francisco, CA, USA; October 29, 2025. **REFERENCES: 1.** Howard JF Jr. *Ann N Y Acad Sci.* 2018;1412(1):113–128. **2.** Grob D, et al. *Muscle Nerve.* 2008;37(2):141–149. **3.** Dewilde S, et al. *BMJ Open.* 2023;13(1):e066445. **4.** Petersson M, et al. *Neurology.* 2021;97:e1382–e1391. **5.** Jones SM, et al. *Clin Exp Neuroimmunol.* 2015;6:32–39. **6.** Meisel A, et al. *Eur J Neurol.* 2024;31(7):e16280. **7.** Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105–16. **ACKNOWLEDGMENTS:** The authors thank the participants and investigators for their participation in the study. Kaushik Kuche, PhD (SIRO Medical Writing Pvt. Ltd., India.) and Doyel Mitra, PhD (Johnson & Johnson) provided the medical writing support. Amit Kavle (SIRO Medical Writing Pvt. Ltd., India) provided graphic designing support. **DISCLOSURES: Elena Cortés Vicente:** Received consulting/advisory from Argenx BV, Alexion Pharmaceuticals Inc., Janssen Pharmaceuticals Inc., UCB Pharma SA. **Sheryl Pease, Nida Imran, Kavita Gandhi, Ibrahim Turkoz, Charlotte Gary, Zia Choudhry,** and **Sindhu Ramchandren:** Employees of Johnson & Johnson, may hold stocks/stock options in Johnson & Johnson. **Maria Ait-Tihyaty:** Employee of Johnson & Johnson at the time of study. **Geoffroy Coteur:** Owner of IPATH Solutions and received consultant fees from Johnson & Johnson. **John Vissing:** Participated in paid advisory boards for Alexion Pharmaceuticals Inc., Argenx BV, Dianthus Therapeutics, Horizon Therapeutics (now Amgen Inc.), Janssen, Regeneron, Roche, and UCB Pharma SA. Previously presented at European Academy of Neurology (EAN) 2025; Helsinki, Finland; June 21–24, 2025.