# Assessment of Patient-Reported Outcomes from the Phase 3 Vivacity-MG3 Study of Nipocalimab in gMG

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, Spain; [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 the study

## Introduction

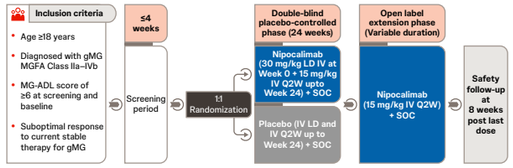
- Generalized myasthenia gravis (gMG) is a rare, chronic, immunoglobulin G (IgG)-mediated autoimmune disease that causes fluctuating and potentially life-threatening muscle weakness[1,2]
- It significantly impacts multiple domains of patient health, with greater disease severity linked to poorer health-related 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]

## Objectives

- 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 two 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 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**

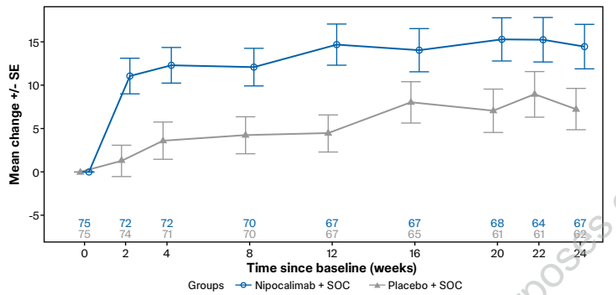
| PRO Measure | Scoring Range | Interpretation |
|---|---|---|
| EQ-5D-5L VAS[a] | 0–100 | Higher scores indicate better health |
| PGIS[b]-Fatigue | 1 (none) – 5 (very severe) | Higher scores indicate more severe fatigue |
| PGIC[c]-Fatigue | 1 (much better) – 7 (much worse) | Higher scores indicate 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; **PGIC**=Patient global impression of change; **PGIS**=Patient global impression of severity; **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% 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

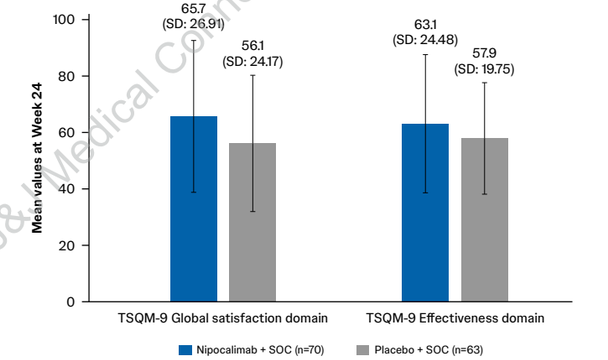
**Figure 2: Mean change in EQ-5D-5L VAS scores across 24 weeks**




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 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 [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

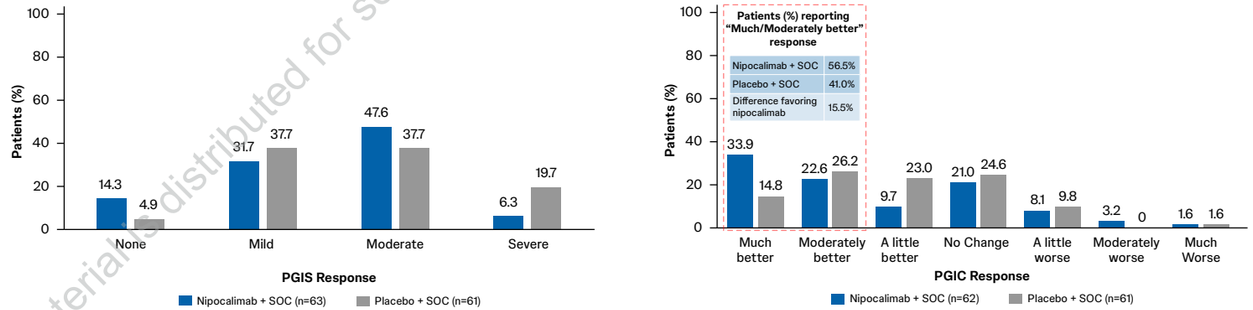
**Figure 4: PRO scores per TSQM-9 scale at Week 24**




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 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". **PGI**=Patient Global Impression; **PGIC**=Patient Global Impression of Change; **PGIS**=Patient Global Impression of Severity; **PRO**=Patient-reported outcomes; **SOC**=Standard-of-care.

## Conclusions

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

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**Maria Ait-Tihyaty:** Employee of Johnson & Johnson at the time of study. Currently employed at Dianthus Therapeutics, Inc.

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EPO-300

Autoantibody: MG