Fatigue Assessed by Neuro-Quality of Life in Phase 3 Vivacity-MG3 Trial of Nipocalimab versus Placebo in Generalized Myasthenia Gravis

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Background

- Generalized myasthenia gravis (gMG) is a rare, chronic autoimmune disorder characterized by impaired neuromuscular transmission mediated by immunoglobulin-G (IgG) autoantibodies.[1]
  - This condition leads to fatigue and muscle weakness in the bulbar, respiratory, and axial muscles, adversely impacting patients' daily functioning and health-related quality of life.[1,2]
- The Neuro-QoL (Quality of Life in Neurological Disorders) assessment provides a standardized, validated tool to capture patients' experiences of disease, functioning, and impact of the treatment across neurological conditions.[3]
- Nipocalimab is a highly selective neonatal Fc receptor blocker, designed to rapidly and sustainably lower circulating IgG levels without disrupting other immunoglobulin classes or compromising immune function.[4]
  - In the Phase 3 Vivacity-MG3 study (**Figure 1**), nipocalimab + standard of care (SOC) demonstrated significant sustained disease control when compared with placebo + SOC over 24 weeks, as measured by improvements in the Myasthenia Gravis-Activities of Daily Living (MG-ADL) score.[5]
  - These findings supported the recent approval of nipocalimab by the United States Food and Drug Administration and European Union for treating adult and pediatric patients (≥12 years) with gMG who are positive for anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibodies.[6,7]

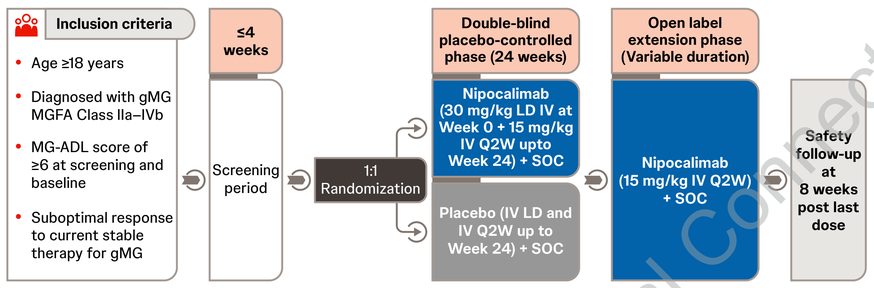
Objectives

- **To assess fatigue and its related effects, as measured by Neuro-QoL Fatigue scale and its association with disease severity in gMG patients treated with nipocalimab + SOC and placebo + SOC in the Vivacity-MG3 study**

Methods

- Least square (LS) mean change from baseline (CFB) in Neuro-QoL Fatigue scores over 24 weeks were compared using a mixed-model repeated measures approach.
- Proportion of patients achieving meaningful within person improvement (MWPI; defined as ≥6.7-point improvement from baseline[8]) at Week 24 were compared between treatment arms using Chi-square test.
- The likelihood of sustained MWPI over ≥8, 12, 16, or 20 weeks was evaluated using logistic regression models.
- Mean CFB at Week 24 was evaluated by stratifying patients based on baseline disease severity scores above the median on both the MG-ADL and Quantitative Myasthenia Gravis (QMG) scales.
  - Severe disease was defined as MG-ADL >9 and QMG >15.

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.

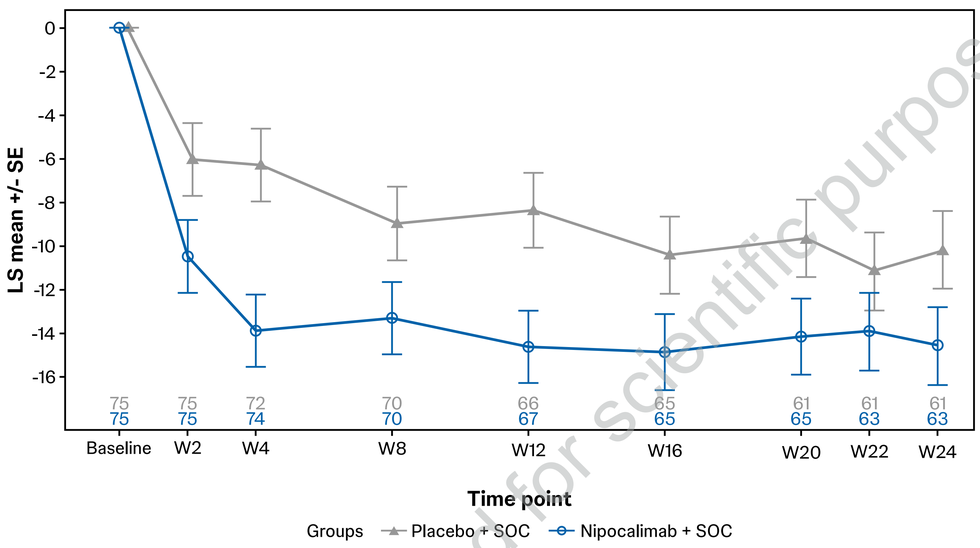
Key Takeaways

- **Nipocalimab-treated patients demonstrated improvements on Neuro-QoL Fatigue score as early as Week 2 when compared with placebo-treated patients.**
- **A higher proportion of patients sustained improvements in Neuro-QoL Fatigue scores (over ≥20 weeks) with nipocalimab + SOC compared with placebo + SOC.**
- **Improvement in Neuro-QoL Fatigue scores were greater in nipocalimab-treated patients compared with placebo-treated patients with severe baseline disease, highlighting the importance of achieving fatigue improvement as a part of overall gMG management.**

Results

- Larger improvements from baseline in Neuro-QoL Fatigue were observed with nipocalimab + SOC compared with placebo + SOC by Week 2 (LS mean difference= −4.4 [95% CI: −8.88; 0.09]; p=0.055; **Figure 2**).
- Improvement with nipocalimab + SOC was sustained through Week 24.
  - At Week 24, numerically greater improvement in Neuro-QoL Fatigue scores was observed with nipocalimab + SOC when compared with placebo + SOC (LS mean difference = −4.3 [95% CI: −9.16; 0.62]; p=0.087; **Figure 2**).

Figure 2: LS mean CFB over time in Neuro-QoL Fatigue scores



CFB=Change from baseline, **LS**=Least square, **Neuro-QoL**=Quality of Life in Neurological Disorders, **SE**=Standard error, **SOC**=Standard of care, **W**=Week.

- Among patients with more severe baseline disease (MG-ADL >9 and QMG >15), mean improvement in fatigue was numerically greater with nipocalimab + SOC vs placebo + SOC at Week 24 (**Table 1**).

Table 1: Mean CFB in Neuro-QoL Fatigue scores in patients with MG-ADL >9 and QMG >15

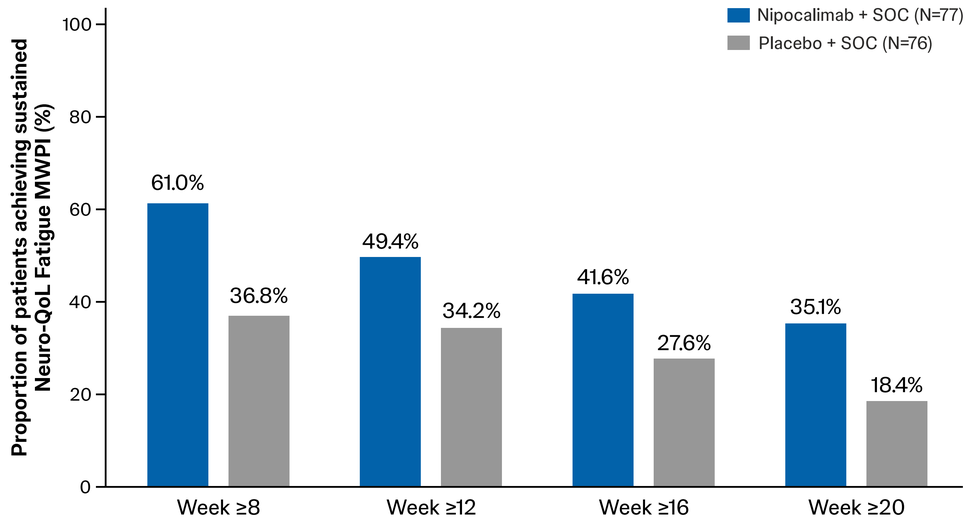
Analysis Visit	Treatment	Observed		CFB		Mean CFB difference (95% CI)
		N	Mean (SD)	N	Mean (SD)	
Baseline	Placebo + SOC	15	62.9 (14.36)	-	-	-
	Nipocalimab + SOC	19	68.0 (11.98)	-	-	
Week 12	Placebo + SOC	13	54.1 (13.56)	13	−9.5 (15.21)	−8.4 (−18.58; 1.88)
	Nipocalimab + SOC	16	50.3 (11.49)	16	−17.8 (11.66)	
Week 24	Placebo + SOC	14	53.4 (15.05)	13	−11.3 (15.30)	−9.0 (−22.02; 4.06)
	Nipocalimab + SOC	14	48.1 (17.63)	14	−20.3 (17.42)	

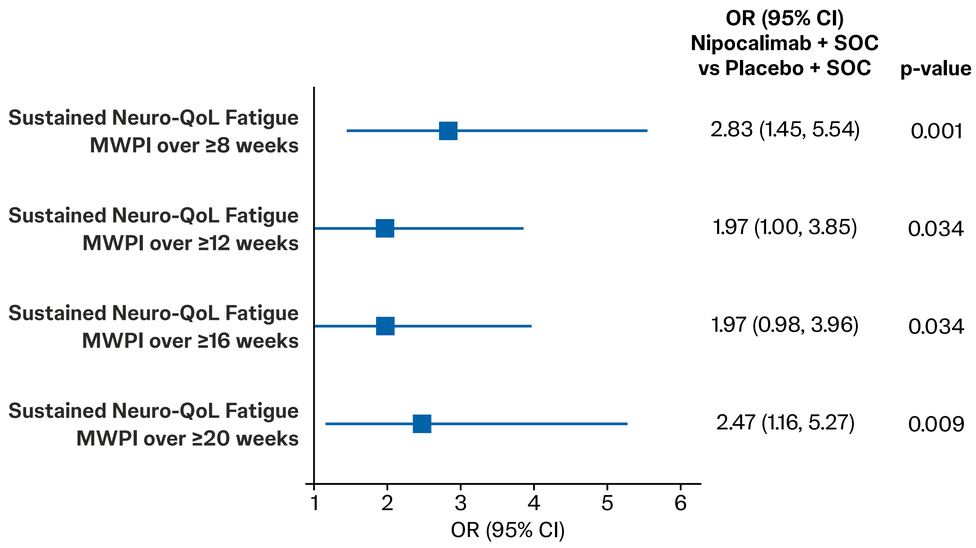
Negative change in score indicates improvement.

CFB=Change from baseline, **CI**=Confidence interval, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **Neuro-QoL**=Quality of life in neurological disorders, **QMG**=Quantitative myasthenia gravis, **SD**=Standard deviation, **SOC**=Standard of care.

- In nipocalimab + SOC arm, 6.2% (95% CI: −10.7, 23.2) more patients achieved Neuro-QoL Fatigue MWPI when compared with placebo + SOC arm at Week 24 (Odds ratio: 1.34; [95% CI: 0.66, 2.75]; p=0.424).
  - 62.7% (42/67) of patients on nipocalimab + SOC met the Neuro-QoL Fatigue MWPI threshold compared to 56.5% (35/62) on placebo + SOC.
- Nipocalimab + SOC-treated patients were approximately twice more likely to sustain Neuro-QoL Fatigue MWPI for a duration of ≥8, 12, 16, and 20 weeks, which was found to be statistically significant (p<0.05) (**Figure 3**).

Figure 3: Proportion of patients achieving sustained Neuro-QoL Fatigue MWPI and the likelihood of achieving sustained Neuro-QoL Fatigue MWPI by duration





CI=Confidence interval, **MWPI**=Meaningful within person improvement, **Neuro-QoL**=Quality of Life in Neurological Disorders, **OR**=Odds ratio, **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.** Gilhus NE, et al. *Nat Rev Dis Primers.* 2019;5:30. **2.** Dresser L, **et al.** *J Clin Med.* 2021;10:2235. **3.** Cella D, et al. *Neurology.* 2012;78(23):1860–7. **4.** Ling LE, et al. *Clin Pharmacol Ther.* 2019;105:1031–9. **5.** Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105–16. **6.** IMAAVY™ (nipocalimab-aahu) injection, for intravenous use. [Package insert] 2025. **7.** European Medicines Agency. Imaavy: nipocalimab. CHMP summary of positive opinion. EMA/CHMP/292567/2025. Published September 19, 2025. Accessed October 3, 2025. https://www.ema.europa.eu/en/medicines/human/EPAR/imaavy. **8.** Raborn A, et al. *Qual Life Res.* Published online June 14, 2025. doi: 10.1007/s11136-025-03998-9. **ACKNOWLEDGEMENTS:** 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. Layout design and reformatting for this encore presentation was provided by Ganesh Karpe (SIRO Medical Writing Pvt. Ltd., India). **DISCLOSURES: John Vissing:** Received consultant fees for serving on advisory boards for Alexion Pharmaceuticals Inc., Argenx BV, Dianthus Therapeutics, Horizon Therapeutics (now Amgen Inc.), Janssen, Regeneron, Roche, and UCB Pharma SA **Kavita Gandhi, Sheryl Pease, Nida Imran, Ibrahim Turkoz, Charlotte Gary, Zia Chaudhry, 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 the study. Currently employed at Dianthus Therapeutics, Inc. **Geoffroy Coteur:** Owner of IPATH Solutions and received consultant fees from Johnson & Johnson. This study was sponsored by Johnson & Johnson. Previously presented at European Academy of Neurology (EAN) 2025; Helsinki, Finland; June 21–24, 2025.