EPO-1052

# Corticosteroid Use in Nipocalimab-Treated Japanese Patients with Generalized Myasthenia Gravis: Phase 3 Vivacity-MG3 Open-Label Extension Study

Carlo Antozzi[1], Kavita Gandhi[2], Ibrahim Turkoz[3], Michael Kutch[4], Marie Fitzgibbon[5,*] Sindhu Ramchandren[3], Hiroyuki Murai[6]

[1]Immunotherapy and Apheresis Departmental Unit, IRCCS Neurological Institute Foundation C. Besta Via G. Milan, Italy; [2]Johnson & Johnson, Horsham, PA, USA; [3]Johnson & Johnson, Titusville, NJ, USA; [4]Cytel, Inc, Cambridge, MA, USA; [5]Johnson & Johnson, Raritan, NJ, USA; [6]Department of Neurology, International University of Health and Welfare, Narita, Japan

*Presenting author

https://www.congresshub.com/Neuroscience/EAN2026/Nipocalimab/Fitzgibbon

**Scan the QR code**
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.



## Key Takeaways

- **During the VIVACITY-MG3 OLE phase, over half of Japanese patients reduced their corticosteroid dose, with substantial proportions receiving low-dose corticosteroid (≤5mg/day)**
- **Minimal symptoms were observed with nipocalimab among patients who reached low doses of steroids**
- **The results from this OLE are preliminary; larger studies are warranted to confirm the findings and to further explore the steroid-sparing potential of nipocalimab**

## Introduction

- Generalized myasthenia gravis (gMG), a rare chronic condition, is characterized by pathogenic immunoglobulin G (IgG) autoantibody-mediated impairment of neurotransmission leading to fatigable muscle weakness[1,2]
- Nipocalimab is a fully human monoclonal antibody that binds the neonatal Fc receptor (FcRn) with high affinity and specificity, reducing circulating levels of IgG, including pathogenic IgG-based autoantibodies[3,4]
- In seropositive adults with gMG, nipocalimab plus standard-of-care (SOC) treatment demonstrated sustained disease control versus placebo plus SOC during the 24-week double-blind phase of the VIVACITY-MG3 study[5,6]
  - Sustained disease control was maintained through open-label extension (OLE) week 60[7]
  - During the OLE, 45% of patients receiving nipocalimab reduced or discontinued corticosteroids; a substantial proportion demonstrated minimum symptom expression (MSE; MG-Activities of Daily Living [MG-ADL] score=0/1) and sustained for ≥8 weeks[7]
- In Japan, achieving minimal symptoms with low corticosteroid doses (≤5mg/day) is an important treatment goal in gMG

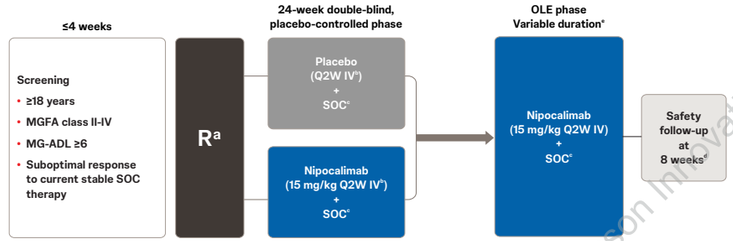
## Objective

**To characterize the impact of nipocalimab on corticosteroid use in patients, specifically in Japanese patients, during the OLE phase of the VIVACITY-MG3 study**

## Methods

- Vivacity-MG3 (NCT04951622) is a double-blind, randomized, placebo-controlled, multicenter, phase 3 study evaluating efficacy and safety of nipocalimab in adults with gMG[5]
  - Tapering of concomitant gMG medications was allowed only in the OLE phase at every 4 weeks, if the disease has been stable in the past 4 weeks as reflected by MG-ADL scores and based on the investigator's discretion

**Figure 1: Study Design[5]**




[a]Randomization was stratified by autoantibody status (anti-AChR+ and/or anti-MuSK+, anti-AChR negative and anti-MuSK negative), Day 1 MG-ADL total score (≤9, >9), and region (East Asia, US, rest of world). The analysis plan, however, grouped all seropositives together (AChR+, MuSK+ or LRP4+) vs triple seronegatives. [b]All patients received the loading dose of placebo or nipocalimab 30 mg/kg at Week 0 and then started placebo or nipocalimab 15 mg/kg Q2W IV from Week 2 to Week 24. [c]SOC includes acetylcholinesterase inhibitor, glucocorticosteroid, and/or immunosuppressant. [d]Participants who withdraw or discontinue after receiving any amount of study intervention are required to complete a safety follow-up visit 8 weeks after their last dose. [e]In the EU, the OLE phase will be up to 240 weeks. **AChR+**=anti-acetylcholine receptor antibody-positive, **EU**=European Union, **gMG**=generalized myasthenia gravis, **IV**=intravenous, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **MGFA**=Myasthenia Gravis Foundation of America, **MuSK+**=anti-muscle-specific tyrosine kinase antibody-positive, **OLE**=open-label extension, **Q2W**=every 2 weeks, **R**=randomized, **SOC**=standard-of-care.

- Analyses were conducted in Japanese patients who were seropositive (anti-acetylcholine receptor [AChR] positive, anti-muscle-specific receptor tyrosine kinase [MuSK] positive, or anti-lipoprotein-related protein receptor 4 [LRP4] positive)
- Corticosteroid doses (mg/day prednisone-equivalent) were evaluated through OLE data cut-off (August 2024)
- The following assessments were evaluated among patients who received corticosteroids at OLE baseline:
  - Mean steroid dose reduction
  - % of patients reaching ≤5mg/day or ≤10mg/day prednisone equivalent
  - Achievement and maintenance of minimum symptom expression (MSE; MG-ADL score =0/1), among patients who reached ≤5mg/day prednisone equivalent
  - Safety

## Results

### *Patient demographics and baseline characteristics of Japanese patients receiving corticosteroids*

- A total of 11 seropositive Japanese patients received corticosteroids at OLE

**Table 1. Patient demographics and baseline characteristics of Japanese patients receiving corticosteroids[a]**

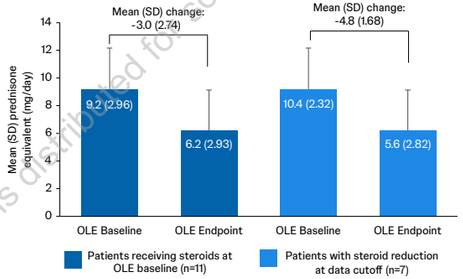
| | Placebo/ Nipocalimab (n=8) | Nipocalimab/ Nipocalimab (n=3) | All Nipocalimab (n=11) |
|---|---|---|---|
| **Age,** mean (SD), years | 59.1 (13.30) | 54.3 (11.85) | 57.8 (12.53) |
| **Sex,** female, n (%) | 7 (87.5) | 3 (100.0) | 10 (90.9) |
| **BMI,** mean (SD), kg/m$^2$ | 28.0 (6.80) | 31.2 (2.10) | 28.9 (5.96) |
| **Baseline MG-ADL total score,** mean (SD) | 9.1 (1.81) | 10.7 (1.53) | 9.5 (1.81) |
| **Baseline QMG total score,** mean (SD) | 16.0 (4.09) | 14.3 (1.76) | 15.5 (3.59) |
| **Antibody positive at screening,** n (%) | | | |
| Anti-AChR+ | 7 (87.5) | 2 (66.7) | 9 (81.8) |
| Anti-MuSK+ | 0 | 1 (33.3) | 1 (9.1) |
| Anti-LRP4+ | 1 (12.5) | 0 | 1 (9.1) |

[a]Baseline for double-blind period. **AChR**=acetylcholine receptor, **BMI**=body mass index, **LRP4**=low-density lipoprotein receptor-related protein 4, **MG-ADL**=myasthenia gravis activities of daily living, **MuSK**=muscle-specific kinase, **OLE**=open-label extension, **QMG**=quantitative myasthenia gravis, **SD**=standard deviation.

### *Corticosteroid use in Japanese patients during OLE*

- Among 11 patients receiving corticosteroids at OLE baseline, 7 (64%) reduced corticosteroids by data cutoff
- Overall, mean (SD) steroid dose reduced from 9.2 (2.96) to 6.2 (2.93) mg/day prednisone-equivalent (**Figure 2**)
- Among those reducing steroid (n=7):
  - Mean (SD) dose reduced from 10.4 (2.32) to 5.6 (2.82) mg/day prednisone-equivalent
  - 5/7 (71%) reached ≤5mg/day

**Figure 2. Mean corticosteroid dose at OLE baseline and OLE endpoint (data cutoff) among patients receiving corticosteroids**

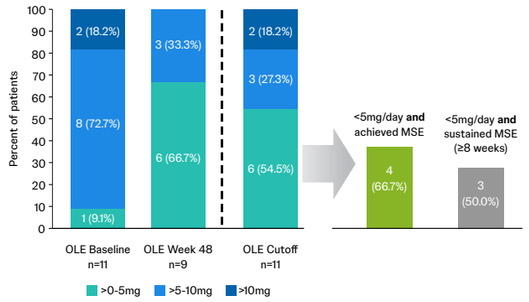



Data cut-off date: August 24, 2024.
**OLE**=open-label extension, **SD**=standard deviation.

### *Distribution of corticosteroid dose groups at OLE baseline, OLE Week 48, and data cutoff*

- Among the 6 patients on ≤5 mg/day prednisone equivalent at data cutoff:
  - 4 (66.7%) achieved MSE by data cutoff
  - 3 (50.0%) achieved sustained MSE (≥8 weeks) by data cutoff

**Figure 3. Distribution of corticosteroid dose groups at OLE baseline, OLE Week 48, and at data cutoff**




Data cut-off date: August 24, 2024 (median follow-up: 76 weeks). Prednisone (mg) at each week equals the mean daily prednisone dose for the 28 days prior to and including that week.
**MSE**=minimum symptom expression, **OLE**=open-label extension.

### *Safety*

- No new safety signals were observed in Japanese patients receiving corticosteroids (**Table 2**)

**Table 2. Summary of TEAEs during the OLE: Japanese patients receiving corticosteroids at OLE baseline**

| | Placebo/ Nipocalimab (n=8) | Nipocalimab/ Nipocalimab (n=3) | All Nipocalimab (n=11) |
|---|---|---|---|
| **Average duration of follow-up,** weeks | 59.36 | 96.81 | 69.57 |
| **All AEs,** n (%) | 8 (100.0) | 3 (100.0) | 11 (100.0) |
| Treatment-related | 4 (50.0) | 1 (33.3) | 5 (45.5) |
| **Serious AEs,** n (%)[a] | 2 (25.0) | 1 (33.3) | 3 (27.3) |
| Treatment-related | 2 (25.0) | 0 | 2 (18.2) |
| **AEs leading to treatment discontinuation,** n (%) | 2 (25.0) | 0 | 2 (18.2) |
| **Infections and Infestations,** n (%) | 7 (87.5) | 1 (33.3) | 8 (72.7) |
| **Infusion-related reactions,** n (%) | 0 | 0 | 0 |
| **Adjudicated MACE,** n (%) | 0 | 0 | 0 |

[a]Serious AEs included hemophagocytic lymphohistiocytosis (n=1) and cellulitis (n=1) in the Placebo/Nipocalimab group, and back pain (n=1) and myasthenia gravis (n=1) in the Nipocalimab/Nipocalimab group
Data cut-off date: August 24, 2024. **AE**=adverse event, **MACE**=major adverse cardiovascular event, **OLE**=open-label extension, **TEAE**=treatment-emergent adverse event.

**PRESENTED AT:** European Academy of Neurology (EAN) Annual Meeting; June 27–30, 2026; Geneva, Switzerland. **REFERENCES: 1.** Gilhus NE, et al. *Nat Rev Dis Primers.* 2019;5(1):30. **2.** Dresser L, et al. *J Clin Med.* 2021;10:2235. **3.** Leu JH, et al. *Front Neurosci.* 2024;18:1302714. **4.** Ling LE, et al. *Clin Pharmacol Ther.* 2019;105(4):1031–1039. **5.** Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105–116. **6.** Yu T, et al. *Eur J Neurol.* 2026;33(5):e70599. **7.** Antozzi C, et al. Presented at: American Academy of Neurology (AAN) Annual Meeting; April 5–9, 2025; San Diego, CA, USA. **ACKNOWLEDGMENTS:** Medical writing support was provided by Rajani Thakur, PhD, of SIRO Medical Writing Pvt. Ltd., India. Namiko Abe, PhD, of Johnson and Johnson, provided additional editorial support. Layout design support was provided by Mugdha Rokade of SIRO Medical Writing Pvt. Ltd., India, (funded by Johnson & Johnson). This study was sponsored by Johnson & Johnson. **DISCLOSURES: Carlo Antozzi:** received travel funding, meeting attendance, and advisory board participation from Alexion, argenx, Johnson & Johnson, Momenta, Sanofi, and UCB. **Kavita Gandhi, Ibrahim Turkoz, Marie Fitzgibbon and Sindhu Ramchandren:** are employees of Johnson & Johnson and may hold stocks/stock options in Johnson & Johnson. **Michael Kutch:** is an employee of Cytel, Inc, MA and may hold stocks/stock options in Cytel. **Hiroyuki Murai:** is on scientific advisory board from Alexion, argenx, and UCB. Has received speaker honoraria from Novartis, Johnson & Johnson, and Merck. Received research support from Ministry of Health, Labour and Welfare, Japan. Received Sciences Research Grant on Rare and Intractable Diseases.