Efficacy of Nipocalimab in Open-Label Extension in Patients Transitioned from Placebo: Results from Vivacity-MG3 Trial

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Key Takeaways

- **Placebo+SOC arm patients who transitioned to nipocalimab+SOC in OLE exhibited early and clinically meaningful improvements that were sustained up to OLE Week 24.**

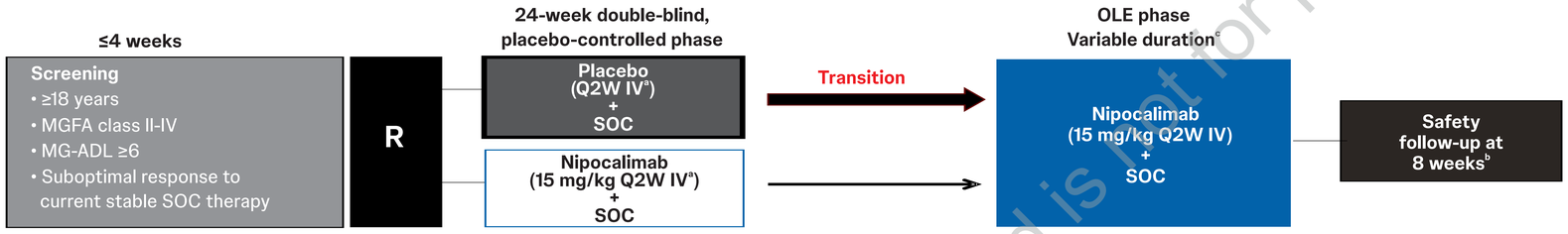
Introduction

- Generalized myasthenia gravis (gMG) is a rare chronic condition characterized by muscle weakness caused by autoantibody-mediated disruption of neurotransmission that severely affects the daily functioning and health-related quality of life.[1,2]
- **Vivacity-MG3 study:** A 24-week, phase 3, randomized, double-blind (DB) study evaluated efficacy and safety of nipocalimab, a monoclonal antibody that blocks neonatal fragment crystallizable receptor (FcRn) to reduce levels of circulating IgG antibodies, added to standard-of-care (SOC) versus (vs) placebo+SOC in patients with gMG.[3]
  - The findings from this study supported the recent United States Food and Drug Administration (U.S. FDA) approval of nipocalimab.[4] The European Medicines Agency Committee for Medicinal Products for Human Use recently (September 2025) recommended authorizing the marketing of nipocalimab added to standard-care therapy for treatment of gMG in adults and adolescents (aged ≥12 years of age) who are anti-AChR or anti-MuSK antibody positive.[5]
- Patients on placebo+SOC in the DB phase of Vivacity-MG3 could transition to receive nipocalimab+SOC in the ongoing open-label extension (OLE) phase.

Objective

To assess the efficacy of nipocalimab+SOC in OLE phase in patients transitioned from placebo+SOC arm of DB phase of the Vivacity-MG3 study.

Study Design



[a]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; [b]Participants who withdraw or discontinue after receiving any amount of study intervention are required to complete a safety follow-up visit 8 wks after their last dose; [c]In the EU, the OLE phase will be up to 240 wks. **DB**=Double-blind; **IV**=Intravenous; **MG-ADL**=Myasthenia Gravis-Activities of Daily Living; **MGFA**=Myasthenia Gravis Foundation of America; **OLE**=Open-label extension; **Q2W**=Every 2 weeks; **R**=Randomized 1:1; **SOC**=Standard-of-care.

Assessments based on MG-ADL and QMG

Assessments

Improvement in MG-ADL and QMG total score from OLE baseline

- Mean changes in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores.
  - Within-group mean changes were examined using paired t-test.
- Proportion of patients achieving meaningful clinical improvements (MCI) (≥2-point improvement[6,7] in MG-ADL total score [MG-ADL-2]).
- Proportion of patients achieving minimal symptom expression (MSE) (MG-ADL score of 0 or 1).
- Proportion of patients with sustained MCI and MSE for ≥8 weeks.
- Percentage of time spent in MCI and MSE.

Results

Population

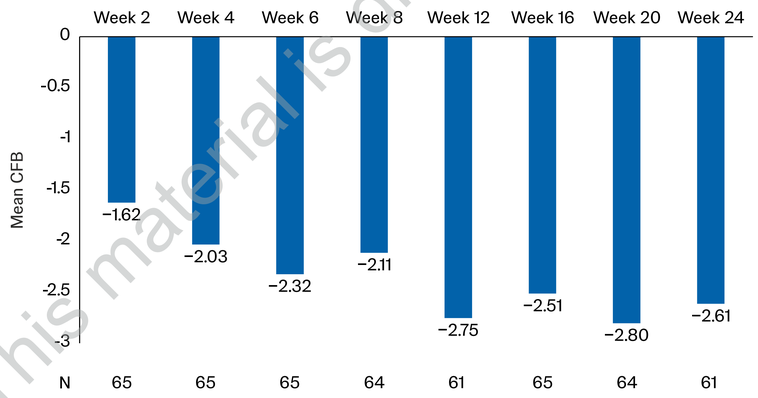
Analysis population and exposure

- Overall, 76 patients from placebo+SOC arm completed DB phase and 66 of them transitioned to nipocalimab+SOC in OLE phase. OLE efficacy analysis set included 66 patients
- Data were collected up to OLE Week 24 (cutoff: 23-August-2024)
- The mean (standard deviation [SD]) duration of nipocalimab exposure was: 68.6 (25.69) weeks, n=66
  - 63 (95.5%) patients had nipocalimab exposure for ≥6 months
  - 46 (69.7%) patients had nipocalimab exposure for ≥12 months

Improvements in MG-ADL score

- Mean (SD) MG-ADL score at OLE baseline[a]: 5.94 (2.95)
- Improvements in **MG-ADL score** were observed **as early as OLE Week 2 (Figure 1)**
- Mean (SD) change from baseline (CFB) in MG-ADL score:
  - **At Week 2:** −1.62 (2.19), p<0.001
  - **At Week 24:** −2.61 (2.62) , p<0.001

Figure 1: Mean improvements in MG-ADL score

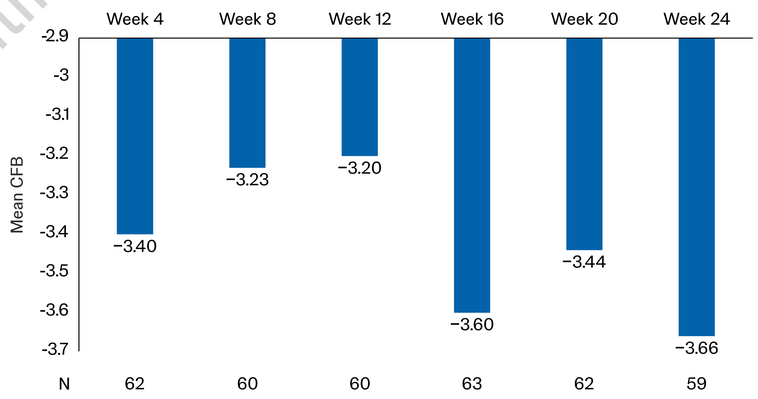


Note: Negative change in score indicates improvement. P-value for comparison of MG-ADL total score change from baseline significantly different from zero using a one-sample t-test. [a]Baseline value is the last value in the double-blind phase. **CFB**=Change from baseline; **MG-ADL**=Myasthenia Gravis-Activities of Daily Living.

Improvements in QMG score

- Mean (SD) QMG score at OLE baseline[a]: 13.42 (5.65)
- Improvements in **QMG score** were observed as early as **OLE Week 4 (Figure 2)**
- Mean (SD) CFB in QMG score:
  - **At Week 4:** -3.40 (3.85), p<0.001
  - **At Week 24:** -3.66 (4.50), p<0.001

Figure 2: Mean improvements in QMG score

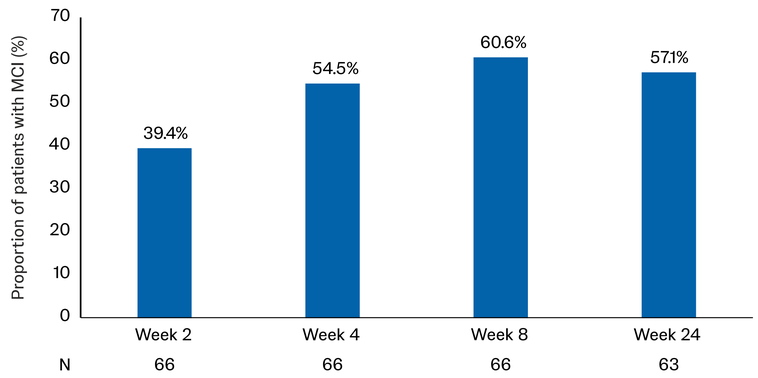


Note: Negative change in score indicates improvement. P-value for comparison of QMG total score change from baseline significantly different from zero using a one-sample t-test. [a]Baseline value is the last value in the double-blind phase. **CFB**=Change from baseline; **QMG**=Quantitative Myasthenia Gravis.

Proportion of patients achieving and sustaining MCI

- At OLE Week 24, **57.1% of patients achieved MCI** in MG-ADL (MG-ADL-2) **(Figure 3)**
  - **Earliest week MCI** (mean [SD]) occurred at **7.3 (13.50) week**
  - **Sustained MCI for ≥8 weeks: 46 (69.7%)** of patients
- **Percentage of time with MCI**
  - **Mean (SD)** percentage of time[b] with MCI up to OLE Week 24: **49.5 (39.20)%**
  - **≥50% study time** with MCI, n (%): **37 (56.1%)** patients
  - **≥75% study time** with MCI, n (%): **28 (42.4%)** patients

Figure 3: Proportion of patients achieving MCI[a] in MG-ADL score through OLE Week 24

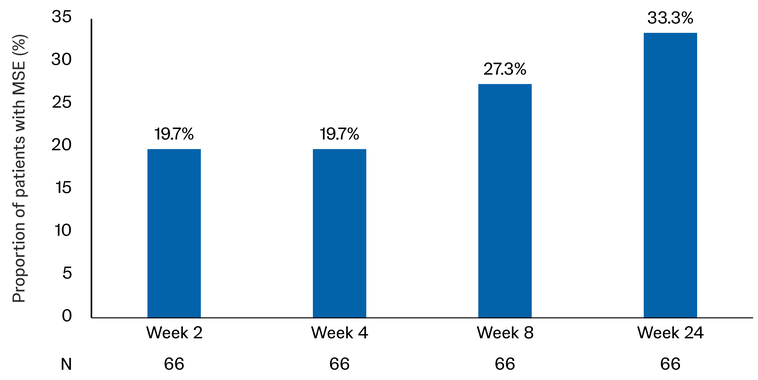


Note: Any patient without a score at a given week were considered as not meeting the MCI conditions.
[a]Minimal clinical improvement is defined as MG-ADL total score improvement of at least 2-points from OLE baseline. [b]Percentage of time with improvement calculated as cumulative days of improvement divided by number of days in OLE up to Week 24. **MCI**=Meaningful clinical improvement; **MG-ADL**=Myasthenia Gravis-Activities of Daily Living; **OLE**=Open-label extension.

Proportion of patients achieving and sustaining MSE

- At OLE Week 24, **33.3% of patients achieved MSE** in MG-ADL (MG-ADL=0 or 1) (**Figure 4**)
  - **Earliest week MSE** (mean [SD]) occurred at **12.1 (18.34) week**
  - **Sustained MSE for ≥8 weeks: 25 (37.9%)** of patients
- **Percentage of time with MSE**
  - **Mean (SD)** percentage of time[b] with MSE up to OLE Week 24: **23.4 (35.30)%**
  - **≥50% study time** with MSE, n (%): **16 (24.2%)** patients

Figure 4: Proportion of patients achieving MSE[a] in MG-ADL score through OLE Week 24



Note: Any patient without a score at a given week were considered as not meeting the MSE conditions.
[a]MSE is defined as MG-ADL score of 0 or 1. [b]Percentage of time with improvement calculated as cumulative days of MSE divided by number of days in OLE up to Week 24. **MG-ADL**=Myasthenia Gravis-Activities of Daily Living; **MSE**=Minimal symptom expression; **OLE**=Open-label extension.

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