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

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DISCLOSURES

Wim Noel

- An employee of Johnson & Johnson and may hold stocks/stock options in Johnson & Johnson

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 FcRn to reduce levels of circulating IgG antibodies, added to standard-of-care (SOC) vs placebo+SOC in patients with gMG[3]
  - The findings from this study supported the recent U.S. FDA approval of nipocalimab[4] and is under EMA/CHMP review
- 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 up to Week 24

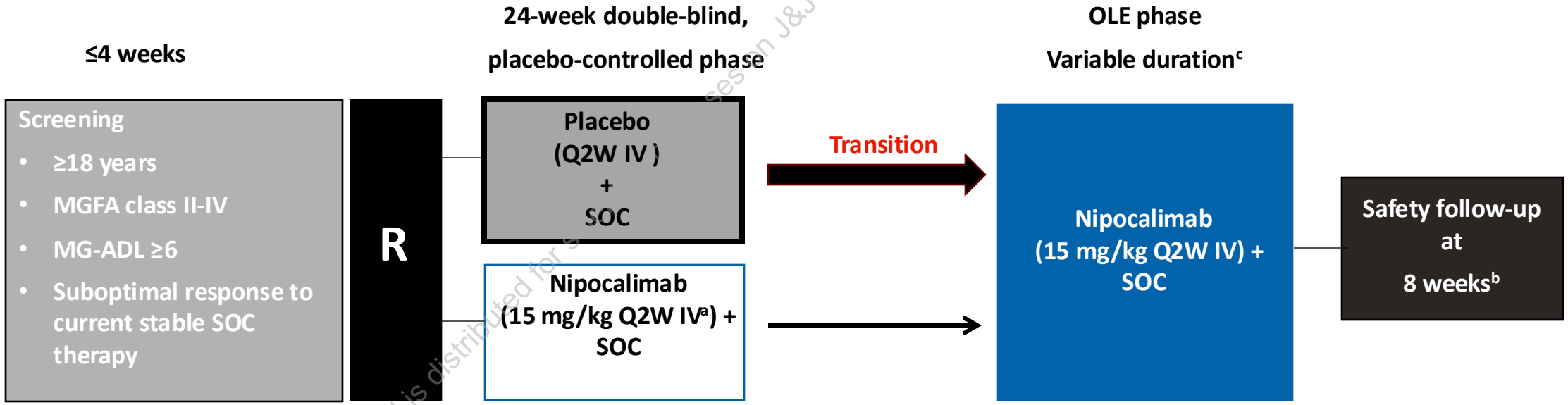
1. Gilhus NE, et al. Myasthenia gravis. *Nat Rev Dis Primers*. 2019;5:30. **2**. Dresser L, et al. *J Clin Med*. 2021;10:2235. **3**. Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105–116. **4**. IMAAVY™ (nipocalimab-aahu) injection for intravenous use [Package Insert] Horsham, PA; Janssen Pharmaceutical Companies, 2025.

FcRn=Neonatal fragment crystallizable receptor; IgG=Immunoglobulin G; U.S FDA=United States Food and Drug Administration.

OBJECTIVE & STUDY DESING

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 nipocalimab 30 mg/kg at Weeek 0 and then started 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.

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METHODS - Assessments based on MG-ADL and QMG

Assessments

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

- Mean changes in MG-ADL and QMG scores
  - Within-group mean changes were examined using paired t-test
- Proportion of patients achieving MCI (≥2-point improvement[1,2] in MG-ADL total score [MG-ADL-2])
- Proportion of patients achieving 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

1. Muppidi S et al., *Muscle Nerve*. 2011;44(5):727–731. **2**. Muppidi S et al., *Ann N Y Acad Sci* 2012;1274:114–119.
MCI=Meaningful clinical improvements; MG-ADL=Myasthenia Gravis-Activities of Daily Living; MSE=Minimal symptom expression; OLE=Open-label extension; QMG=Quantitative Myasthenia Gravis.

RESULTS – Population

Analysis population and exposure

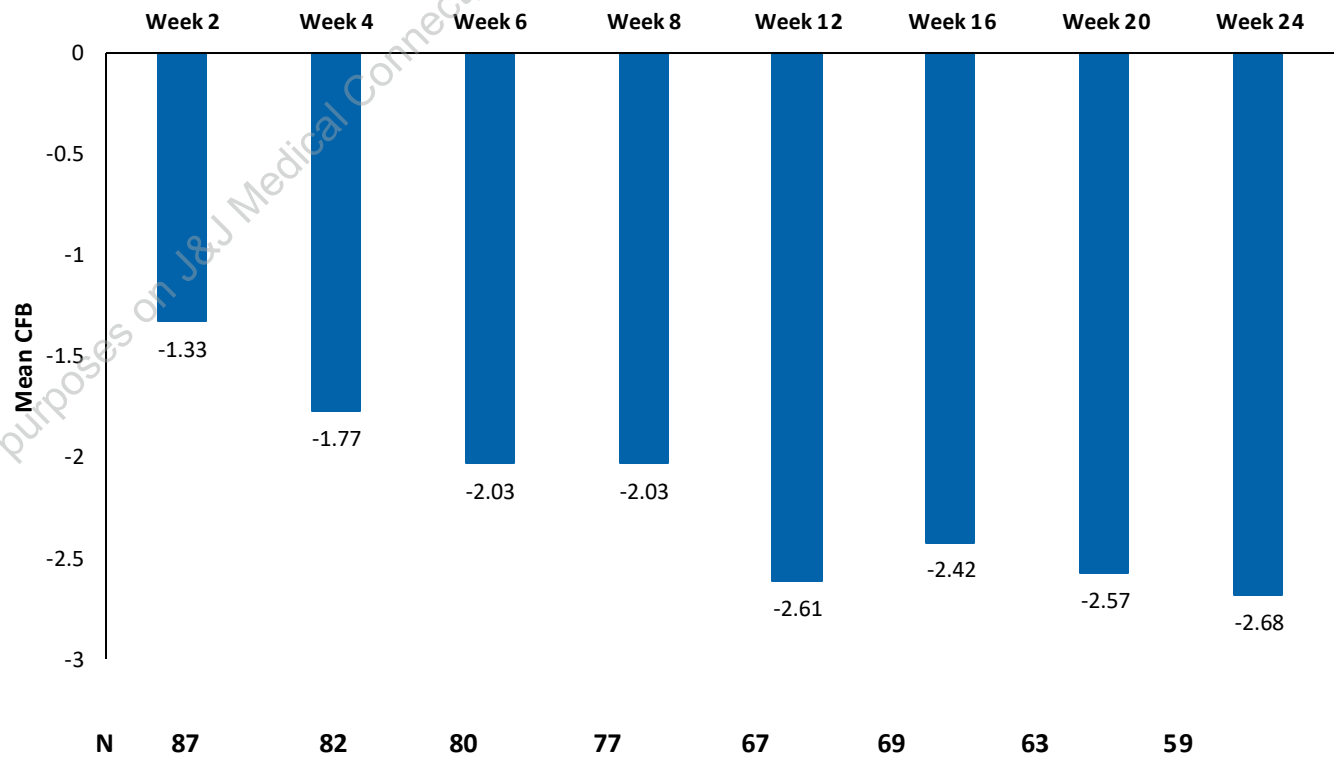
- Overall, 98 patients from placebo+SOC arm of DB phase were transitioned to nipocalimab+SOC arm in OLE. OLE efficacy analysis set included 88 patients
- Data were collected up to OLE Week 24 (cutoff: 23-August-2024)
- The mean (SD) duration of nipocalimab exposure was: 36.1 (23.05) weeks, n=88
  - 68.2% patients had nipocalimab exposure for ≥6 months
  - 29.5% patients had nipocalimab exposure for ≥12 months

DB=Double-blind; OLE=Open-label extension; SD=Standard deviation; SOC=Standard-of-care.

RESULTS – Improvements in MG-ADL score

- Mean (SD) MG-ADL score at OLE baseline[a]: 6.33 (3.37)
- Improvements in **MG-ADL score** were observed **as early as OLE Week 2 (Figure 1)**
- Mean (SD) CFB in MG-ADL score:
  - **Week 2:** −1.33 (2.13), p<0.001
  - **Week 24:** −2.68 (3.26), 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; OLE=Open-label extension; SD=Standard deviation.

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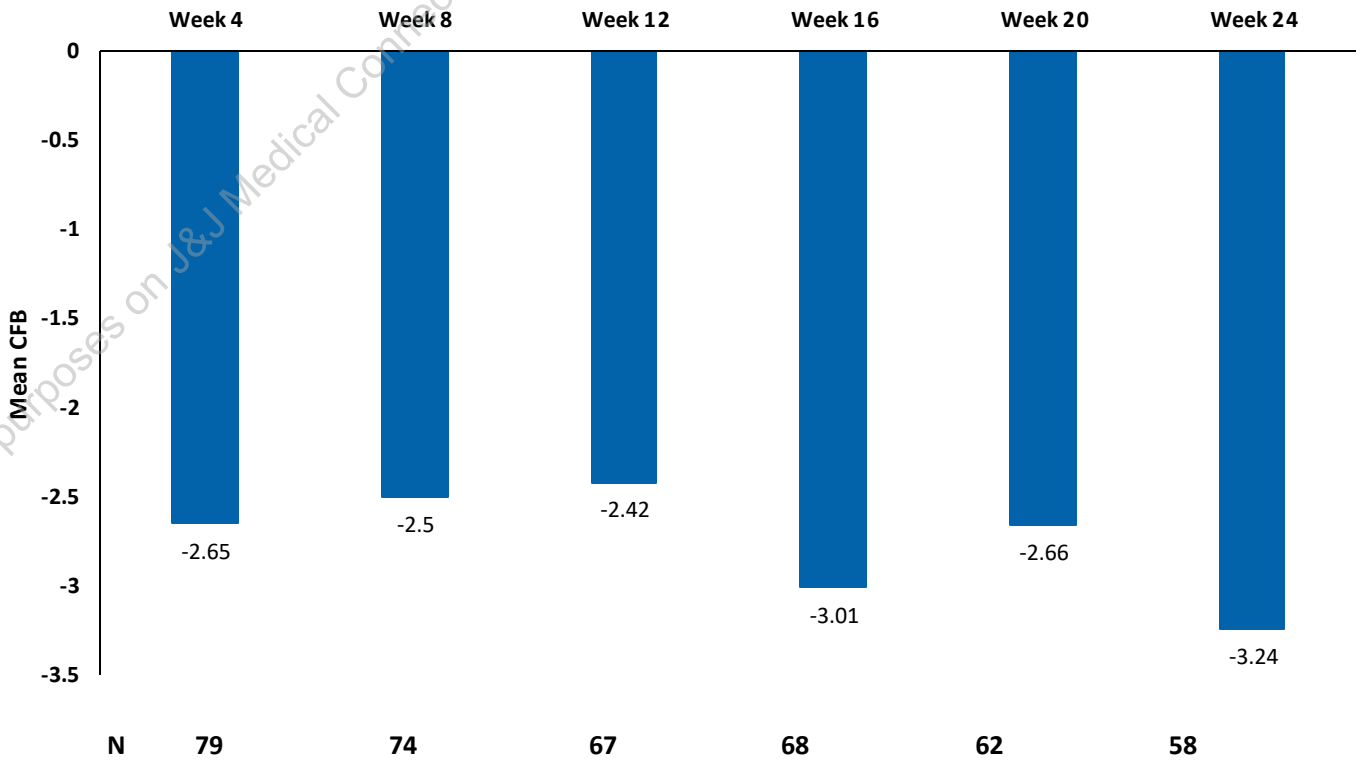
RESULTS – Improvements in QMG score

- Mean (SD) QMG score at OLE baseline[a]: 13.47 (5.70)
- Improvements in **QMG score** were observed as early as **OLE Week 4 (Figure 2)**
- Mean (SD) CFB in QMG score:
  - **Week 4:** −2.65 (3.95), p<0.001
  - **Week 24:** −3.24 (4.95), 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; OLE=Open-label extension; QMG=Quantitative Myasthenia Gravis; SD=Standard deviation.

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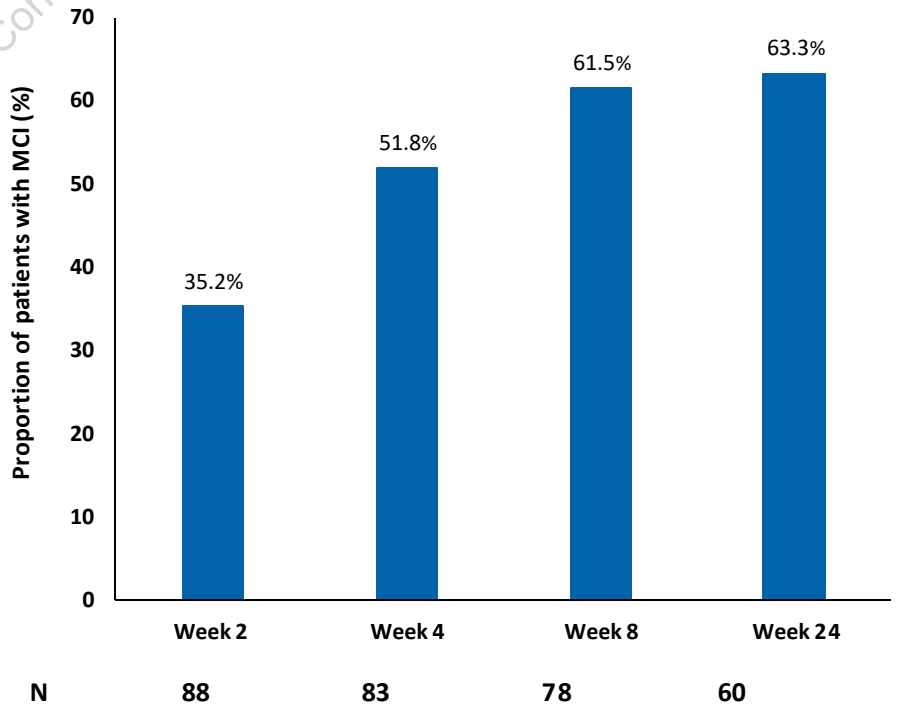
RESULTS - Proportion of patients achieving and sustaining MCI

- At OLE Week 24, **63.3% of patients achieved MCI** in MG-ADL (MG-ADL-2) (**Figure 3**)
  - **Earliest week MCI** (mean [SD]) occurred at **5.1** (4.99) **week**
  - **Sustained MCI for ≥8 weeks: 51.1%** of patients
- **Percentage of time with MCI**
  - **Mean (SD)** percentage of time[b] with MCI up to OLE Week 24: **40.7** (38.7)%
  - **≥50% study time** with MCI, n (%): 39 (**44.3%**) patients
  - **≥75% study time** with MCI, n (%): 30 (**34.1%**) patients

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



[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; SD=Standard deviation; SOC=Standard-of-care.

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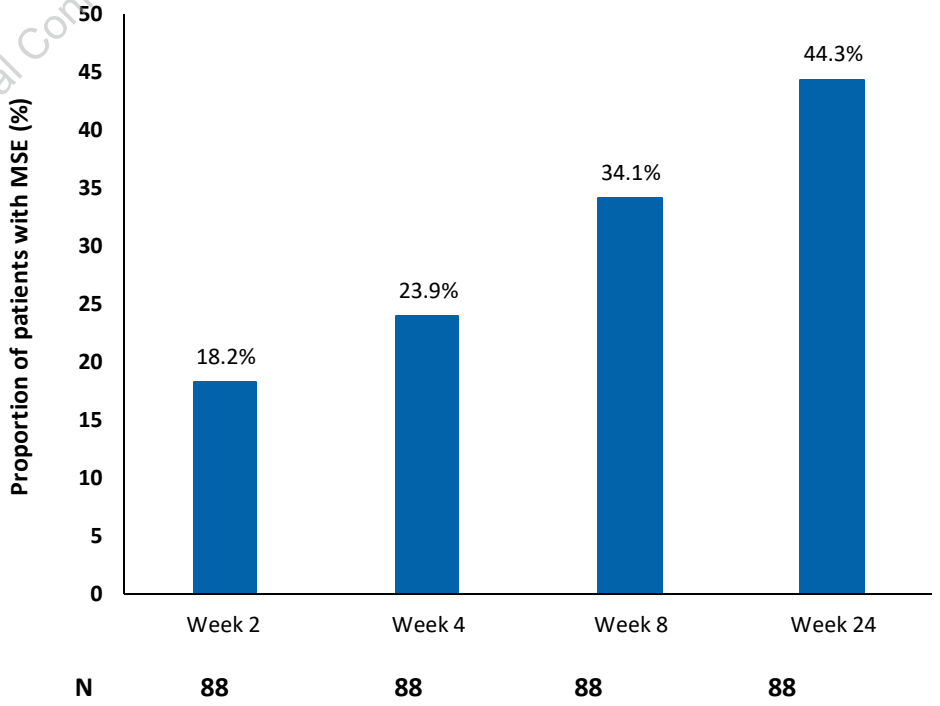
RESULTS - Proportion of patients achieving and sustaining MSE

- At OLE Week 24, **44.3% of patients achieved MSE** in MG-ADL (MG-ADL=0 or 1) (**Figure 4**)
  - **Earliest week** MSE (mean [SD]) occurred **at 7.4 (7.37) week**
  - **Sustained MSE for ≥8 weeks: 22.7%** of patients
- **Percentage of time with MSE**
  - **Mean (SD)** percentage of time[b] with MSE up to OLE Week 24: **17.6** (31.06)%
  - **≥50% study time** with MSE, n (%): **15 (17%)** patients

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



[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; SD=Standard deviation; SOC=Standard-of-care.

CONCLUSIONS

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

OLE=Open-label extension; SOC=Standard-of-care.