Analysis of Long-Term Efficacy of Nipocalimab in Myasthenia Gravis: Open-Label Extension of the 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

- Generalised myasthenia gravis (gMG) is a chronic autoimmune disease caused by autoantibodies targeting the neuromuscular junction
  - It is characterized by generalized weakness in ocular and skeletal muscles affecting the daily functioning and QoL[1,2]
- **Vivacity-MG3 study:** A DB, 24-week, phase 3 study demonstrated statistically significant and clinically meaningful improvements in MG-ADL and QMG scores with nipocalimab+SOC treatment (vs placebo+SOC)[3]
  - The findings from this study supported the recent U.S. FDA approval of nipocalimab[4] and is under EMA/CHMP review
- Patients on nipocalimab+SOC in the DB phase of Vivacity-MG3, could continue to receive active drug in ongoing open-label extension (OLE) allowing the assessment of long-term efficacy of nipocalimab+SOC

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.

DB=Double-blind; MG-ADL=Myasthenia Gravis-Activities of Daily Living; QMG=Quantitative Myasthenia Gravis; QoL=Quality of life; SOC=Standard-of-care.

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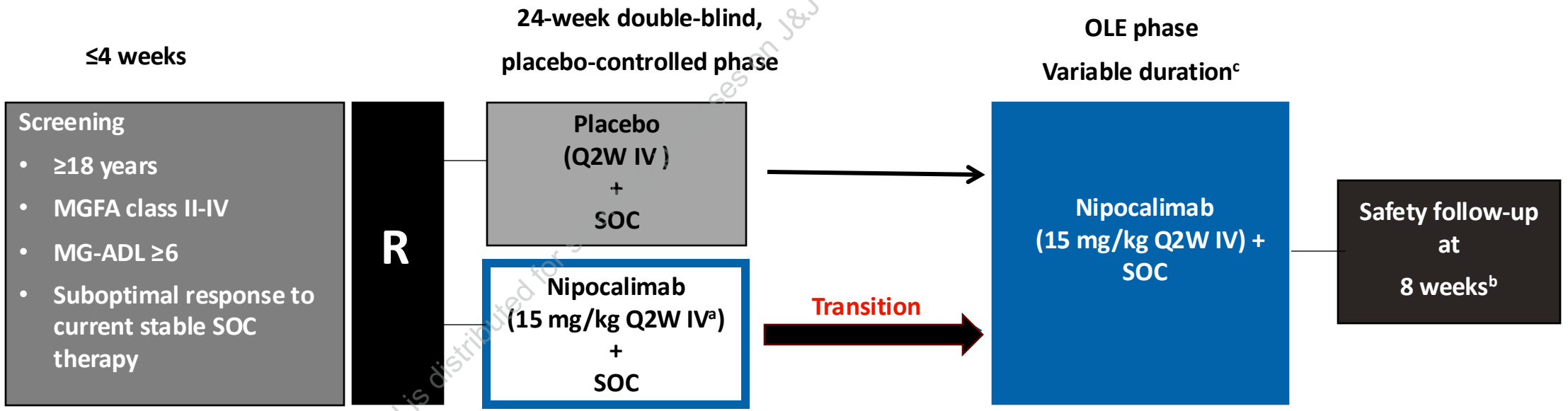
Objective & Study Design

Objective: To assess the long-term efficacy of nipocalimab+SOC in OLE phase in patients transitioned from nipocalimab+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]Patients 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 scores from DB baseline

- Mean changes in MG-ADL and QMG scores at DB Week 24 through Week 48 in OLE
  - 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; SOC= Standard-of-care.

Results – Population

Analysis population and exposure

- Overall, 98 patients from the nipocalimab+SOC arm of DB phase transitioned to nipocalimab+SOC arm of the OLE phase
- Data were collected up to Week 48 (DB 24 weeks + OLE 24 weeks) (cutoff: 23-August-2024)
- The mean (SD) duration of nipocalimab exposure was: 59.9 (24.14) weeks, n=88
  - 97.7% patients had nipocalimab exposure for ≥6 months
  - 59.1% 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 total score

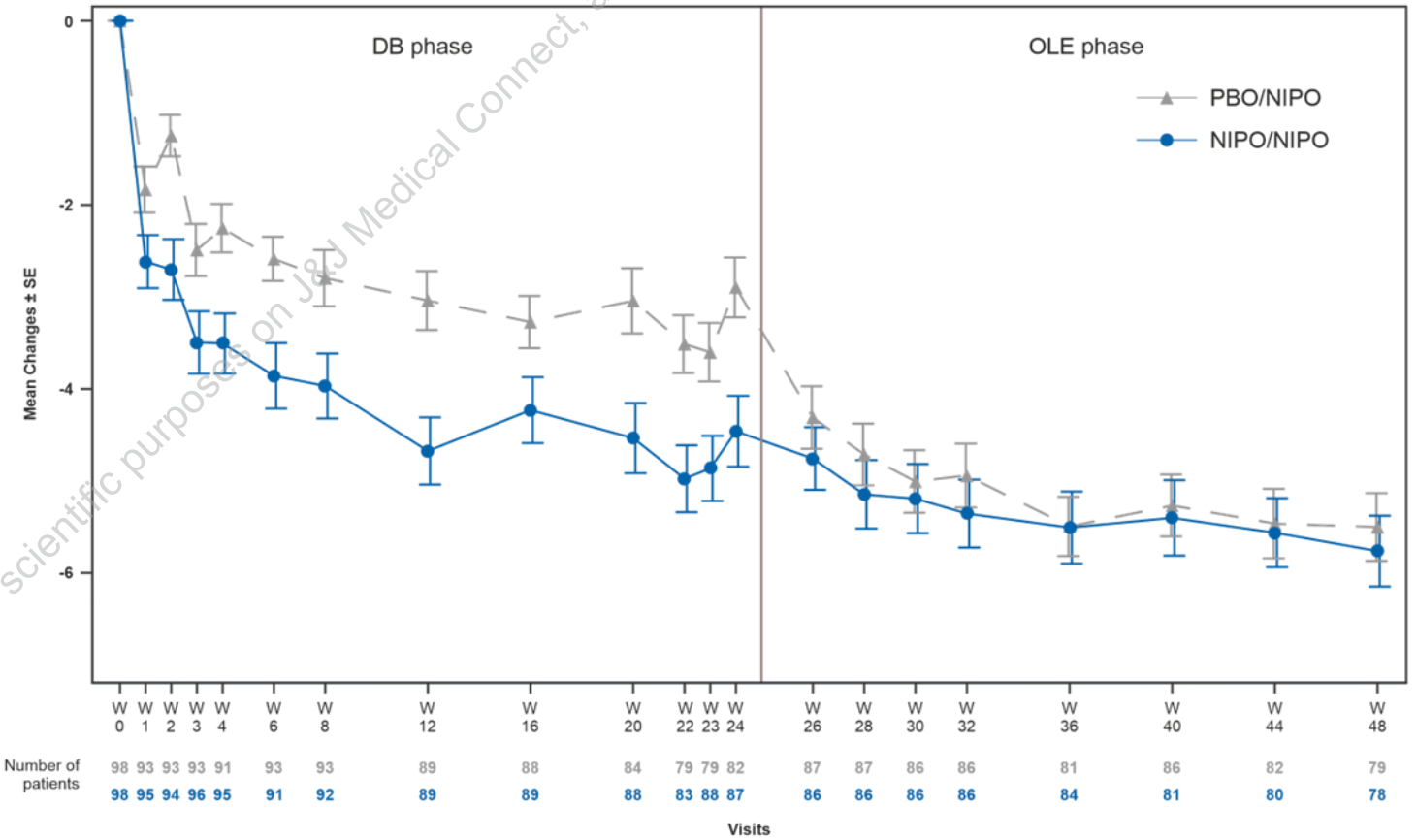
MG-ADL

- Mean (SD) MG-ADL score at DB baseline (Week 0):

  9.5 (2.69)

- Improvements in **MG-ADL score at Week 24** were **maintained through Week 48 (Figure 1)**
- Mean (SD) CFB in MG-ADL score:
  - **Week 24:** −4.46 (3.59), p<0.001
  - **Week 48:** −5.19 (4.06), p<0.001

Figure 1: Mean improvements in MG-ADL score



Note: Negative change in score indicates improvement. PBO/NIPO: patients from PBO+SOC arm of DB phase received NIPO+SOC in OLE phase. NIPO/NIPO: Patients in NIPO+SOC arm in DB phase continued to receive NIPO+SOC in OLE phase. P-value for comparison of MG-ADL total score change from baseline significantly different from zero using a one-sample t-test.

CFB=Change from baseline; DB=Double-blind; MG-ADL=Myasthenia Gravis-Activities of Daily Living; NIPO=Nipocalimab; PBO=Placebo; SD=Standard deviation; SE=Standard error; SOC=Standard-of-care; W=Week.

Results - Improvements in QMG total score

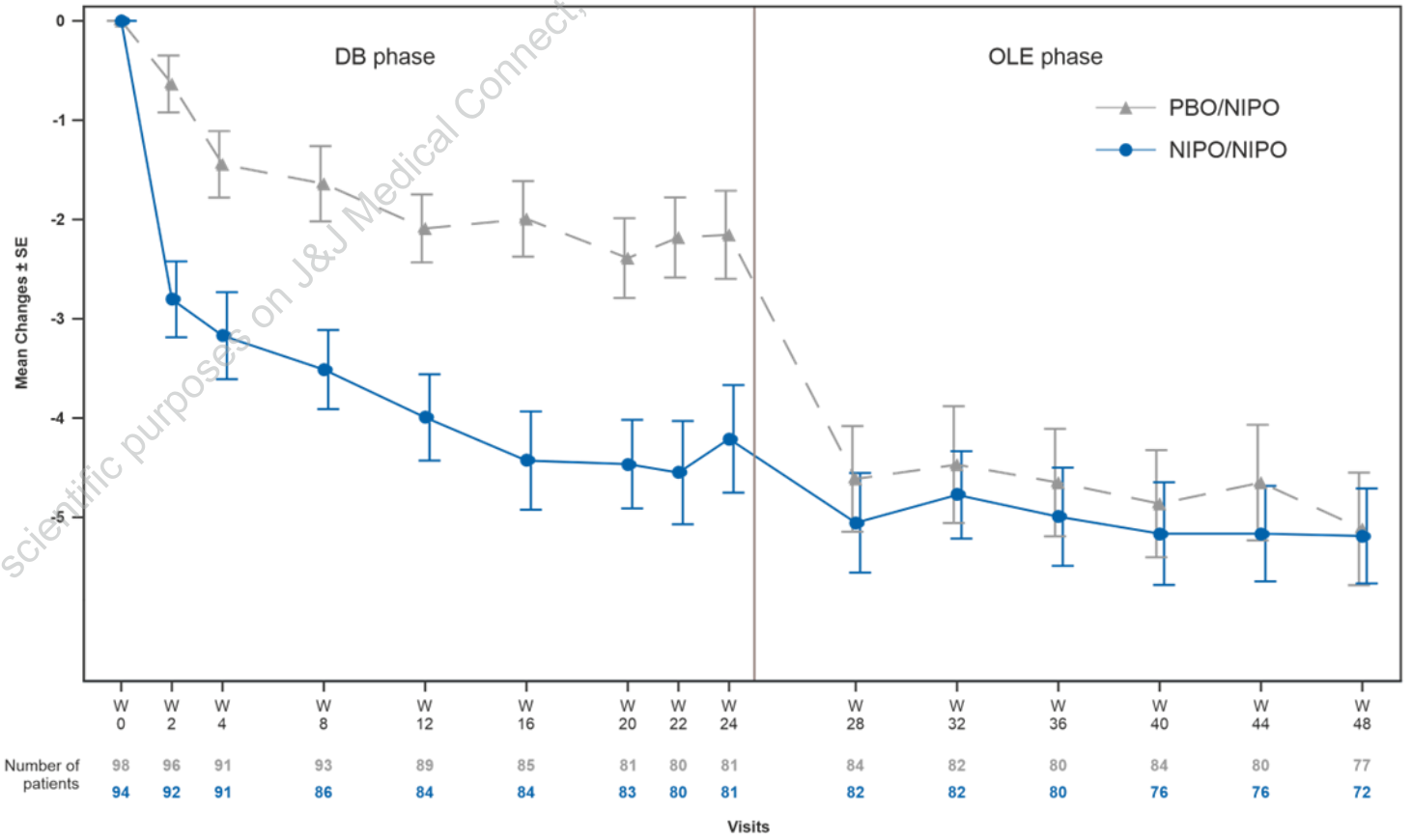
QMG

- Mean (SD) QMG score at DB baseline (Week 0):

  15.0 (4.80)

- Improvements in **QMG score at Week 24** were **maintained through Week 48 (Figure 2)**
- Mean (SD) CFB in QMG score:
  - **Week 24:** −4.21 (4.87), p<0.001
  - **Week 48:** −4.73 (4.45), p<0.001

Figure 2: Mean improvements in QMG score



Note: Negative change in score indicates improvement. . PBO/NIPO; patients from PBO+SOC arm of DB phase received NIPO+SOC in OLE phase. NIPO/NIPO: Patients in NIPO+SOC arm in DBP phase continued to receive NIPO+SOC in OLE phase. P-value for comparison of QMG total score change from baseline significantly different from zero using a one-sample t-test.
CFB=Change from baseline; DB=Double-blind; NIPO=Nipocalimab; PBO=Placebo; QMG=Quantitative myasthenia gravis; SD=Standard deviation; SE=Standard error; SOC=Standard-of-care; W=Week.

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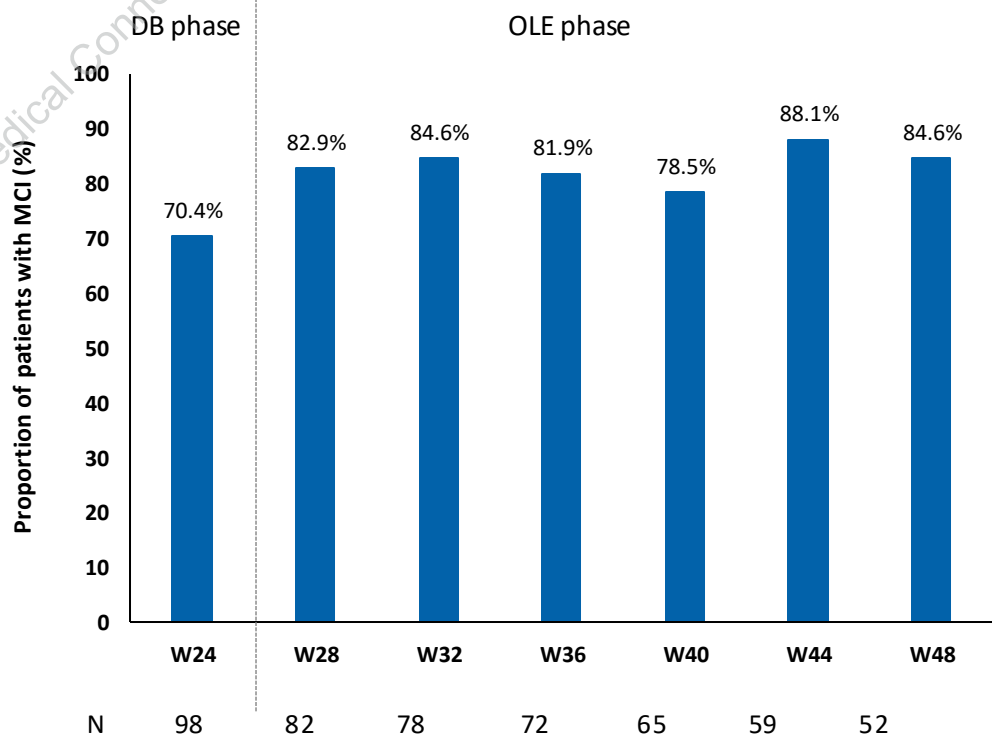
Results - Proportion of patients achieving and sustaining MCI

- At Week 48, **84.6% of patients achieved MCI** in MG-ADL (MG-ADL-2) (**Figure 3**)
- **MCI**
  - **Mean (SD) time to earliest MCI** was **4.0 (**5.95**) weeks**
  - **Sustained MCI for ≥8 weeks** was observed in **77.6**% of patients
- **Percentage of time with MCI**
  - **Mean (SD)** percentage of time[b] with MCI up to Week 48: **71.6 (**34.14**)%**
  - **≥50% study time** with MCI, n (%)**:** 65 **(73.9%)** patients
  - **≥75% study time** with MCI, n (%): 59 **(67.0%)** patients

Figure 3: Proportion of patients achieving MCI[a] in MG-ADL score through week 48

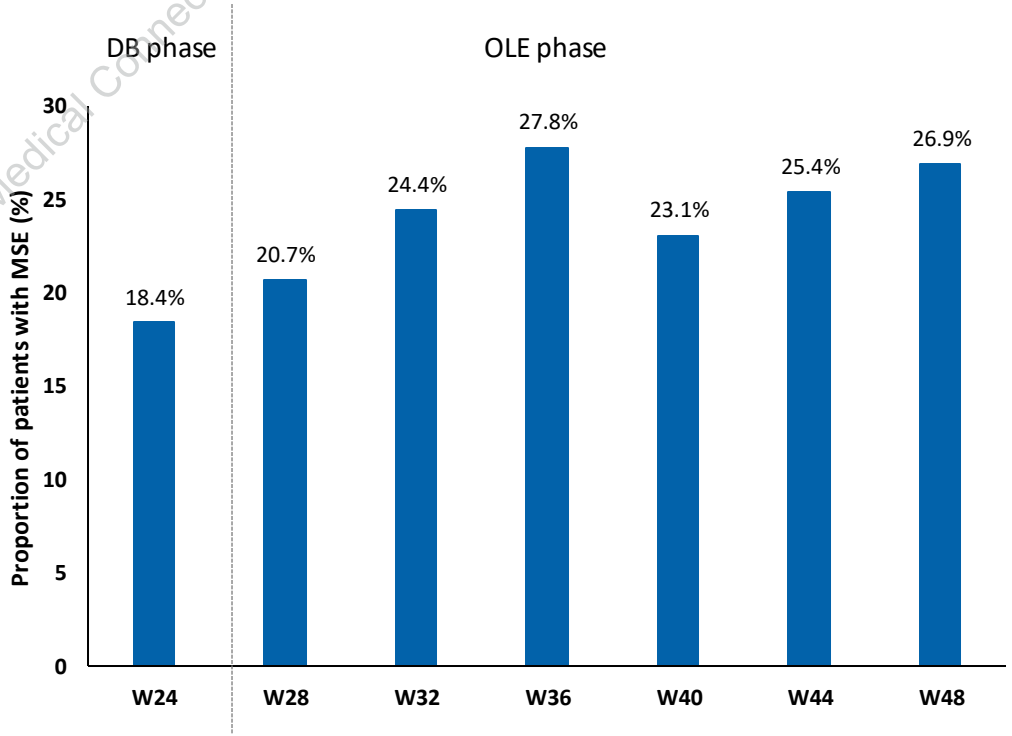


[a]Minimal clinical improvement is defined as MG-ADL total score improvement of at least 2 points from Open-label Phase baseline. [b]Percentage of time with improvement calculated as cumulative days of improvement divided by number of days in study up to OLE Week 24. The number of days in study up to OLE Week 24 is calculated as OLE Week 24 date (or early termination date if earlier) minus DB baseline date.
DB=Double-blind; MCI=Meaningful clinical improvement; MG-ADL=Myasthenia Gravis-Activities of Daily Living; OLE=Open-label extension; SD=Standard deviation.

Results - Proportion of patients achieving and sustaining MSE

- At Week 48, 26.9**% of patients achieved MSE** in MG-ADL (MG-ADL-2) (**Figure 4**)
- **MSE**
  - **Mean (SD) time to earliest** MSE was **14.5** (15.12) **weeks**
  - **Sustained MSE for ≥8 weeks** was observed in **23.5%** of patients
- **Percentage of time with MSE**
  - **Mean (SD)** percentage of time[b] with MSE up to Week 48: **15.9** (30.21)%
  - **≥50% study time** with MSE, n (%): 15 (**17.0%**) patients
  - **≥75% study time** with MSE n (%): 11 (**12.5%**) patients

Figure 4: Proportion of patients achieving MSE[a] in MG-ADL score through week 48



[a]MSE is defined as MG-ADL total score of 0 or 1. [b]Percentage of time with MSE calculated as cumulative days of MSE divided by number of days in study up to OLE Week 24 (i.e., Week 48). The number of days in study up to OLE Week 24 is calculated as OLE Week 24 date (or early termination date if earlier) minus DB baseline date.
DB=Double-blind; MG-ADL=Myasthenia Gravis-Activities of Daily Living; MSE=Minimal symptom expression; OLE=Open-label extension; SD=Standard deviation.

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Conclusions

Patients who **continued nipocalimab+SOC** in OLE phase showed **sustained improvements in MG-ADL and QMG scores** up to Week 48 (i.e., OLE Week 24) of Vivacity-MG3 study

MG-ADL=Myasthenia Gravis-Activities of Daily Living; OLE=Open-label extension; QMG=Quantitative Myasthenia Gravis; SOC=Standard-of-care.