

# Analysis of Long-Term Efficacy of nipocalimab in Myasthenia Gravis: Open-Label Extension of the Vivacity-MG3 Trial

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## Background

- **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 quality of life (QoL)<sup>1,2</sup>
- **Vivacity-MG3 study** is a double-blind (DB), 24-week, phase 3 study demonstrating statistically significant and clinically meaningful improvements in MG-ADL and QMG scores with Nipocalimab + SOC treatment (vs placebo + SOC)<sup>3</sup>. Findings from this study supported the recent U.S. FDA approval of nipocalimab and are currently under EMA review.
- Patients on Nipocalimab + SOC in the DB phase of Vivacity-MG3, could continue to receive active drug in ongoing **open-label extension (OLE)** phase allowing the assessment of long-term efficacy of Nipocalimab + SOC.<sup>3</sup>
- In a **secondary analysis** of Vivacity-MG3 study that included all autoantibody-positive adult patients with gMG transitioned from the DB phase to the OLE phase (total number = 137), nipocalimab demonstrated a sustained disease control **over 84 weeks** (across DB and OLE, as assessed by MG-ADL and QMG scales) in a broad population of autoantibody-positive patients with gMG. In the same analysis, 45% of patients receiving corticosteroids for gMG at OLE phase baseline were able to decrease or discontinue steroids at data cutoff while efficacy was maintained<sup>4,5</sup>

## Objectives

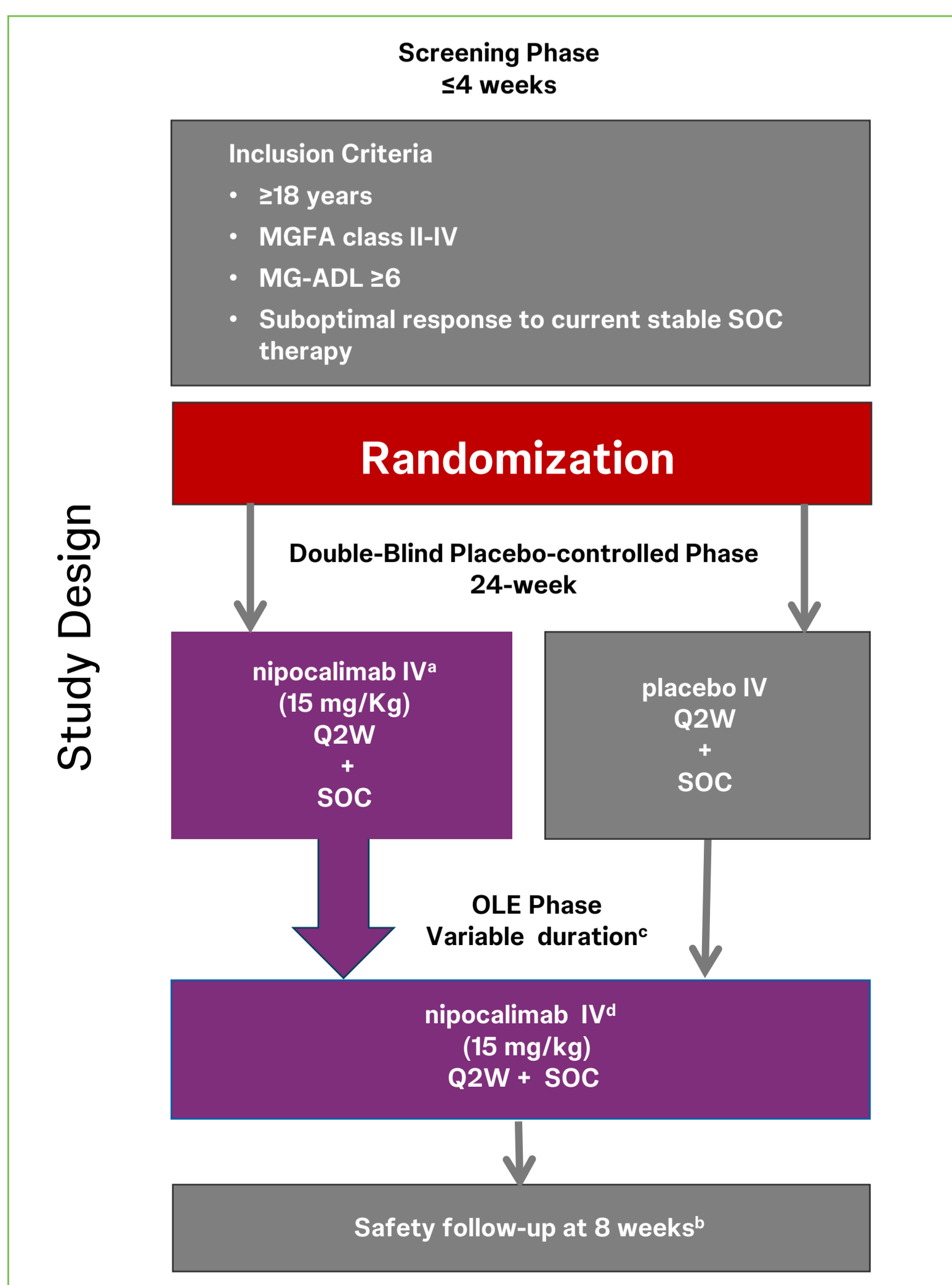
- To assess the **long-term efficacy** of nipocalimab + SOC in OLE phase in patients transitioned from nipocalimab + SOC arm of DB phase of the Vivacity-MG3 study.

## Methods

- **Assessments based on MG-ADL and QMG** were collected in patients treated with nipocalimab + SOC from baseline of DB phase through Week 48 in OLE phase.
- **Data were collected up to Week 48** (DB 24 weeks + OLE 24 weeks) (cutoff: 23-August-2024).

## Assessments

- 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<sup>6,7</sup> 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



## Results

### Analysis Population and Exposure

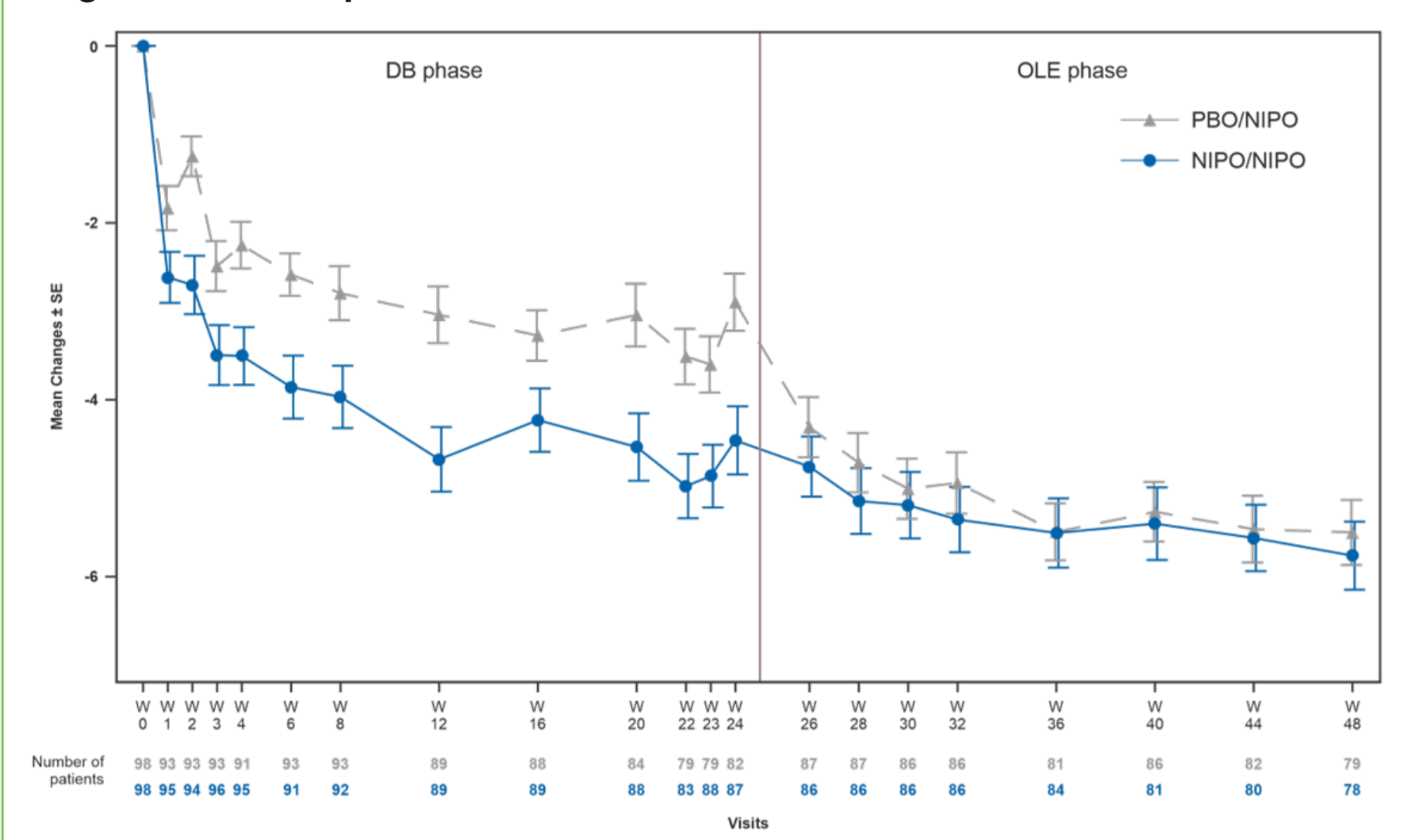
- Overall, **98 patients** from nipocalimab + SOC arm of DB phase transitioned to nipocalimab + SOC in OLE phase
- The mean (SD) **duration of nipocalimab exposure** was: **59.9 (24.14) weeks, n=88**
  - 97.7% patients had nipocalimab exposure for ≥6 months
  - 59.1% patients had nipocalimab exposure for ≥12 months

### Improvement in MG-ADL total score

- 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

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.

Figure 1: Mean improvements in MG-ADL score

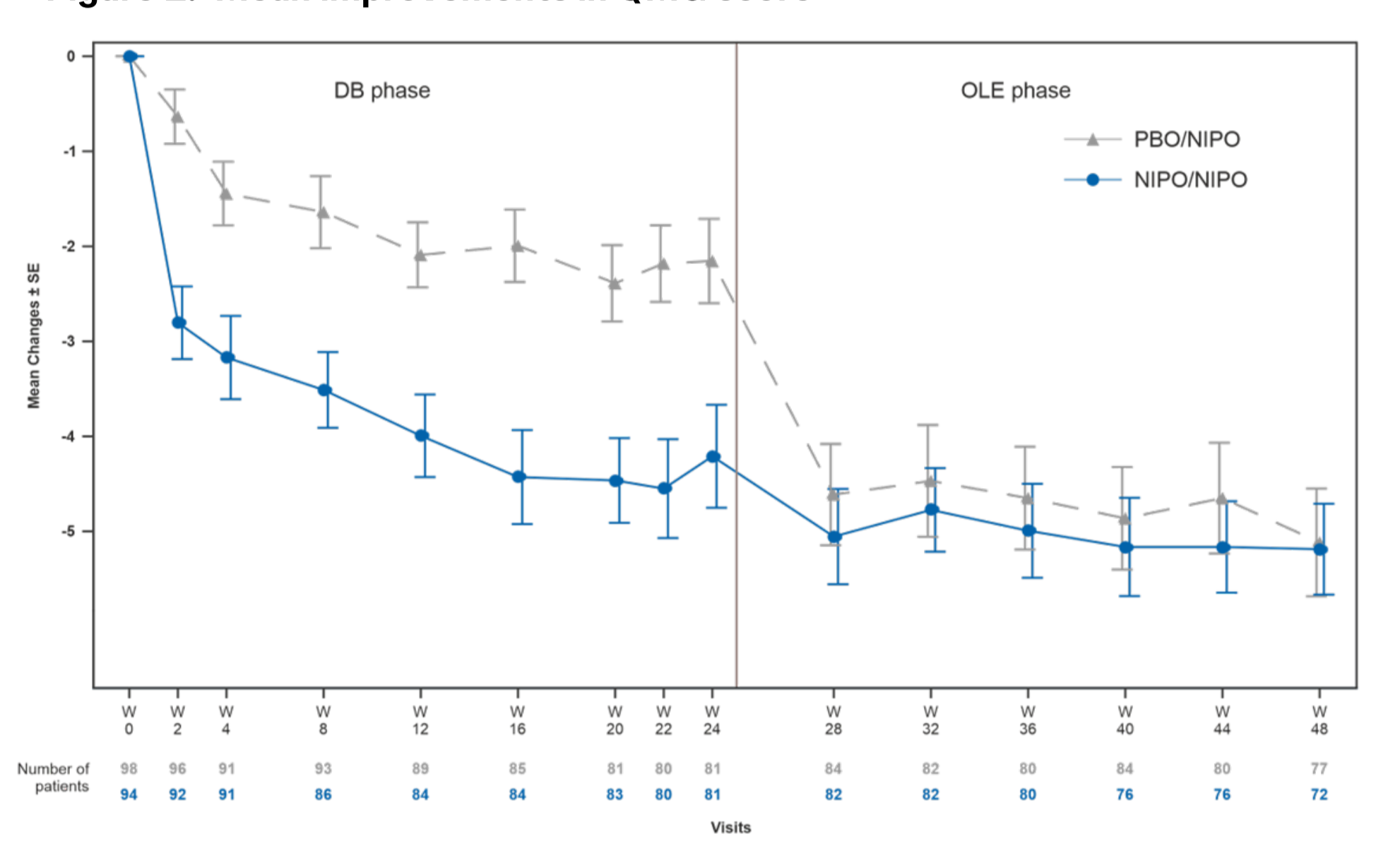


### Improvement in QMG total score

- 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

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 QMG total score change from baseline significantly different from zero using a one-sample t-test.

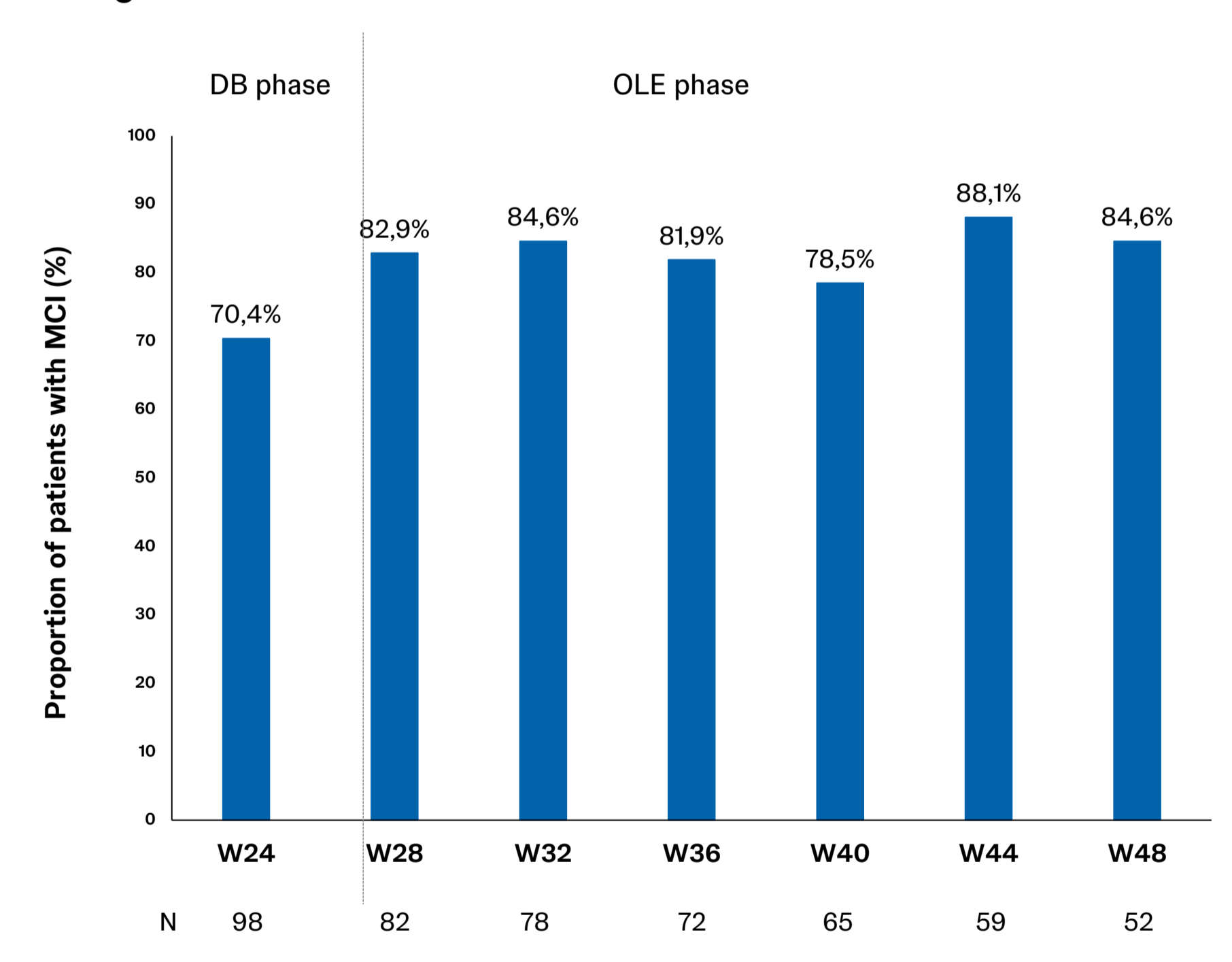
Figure 2: Mean improvements in QMG score



### 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<sup>b</sup> with MCI up to Week 48 was **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<sup>a</sup> in MG-ADL score through week 48

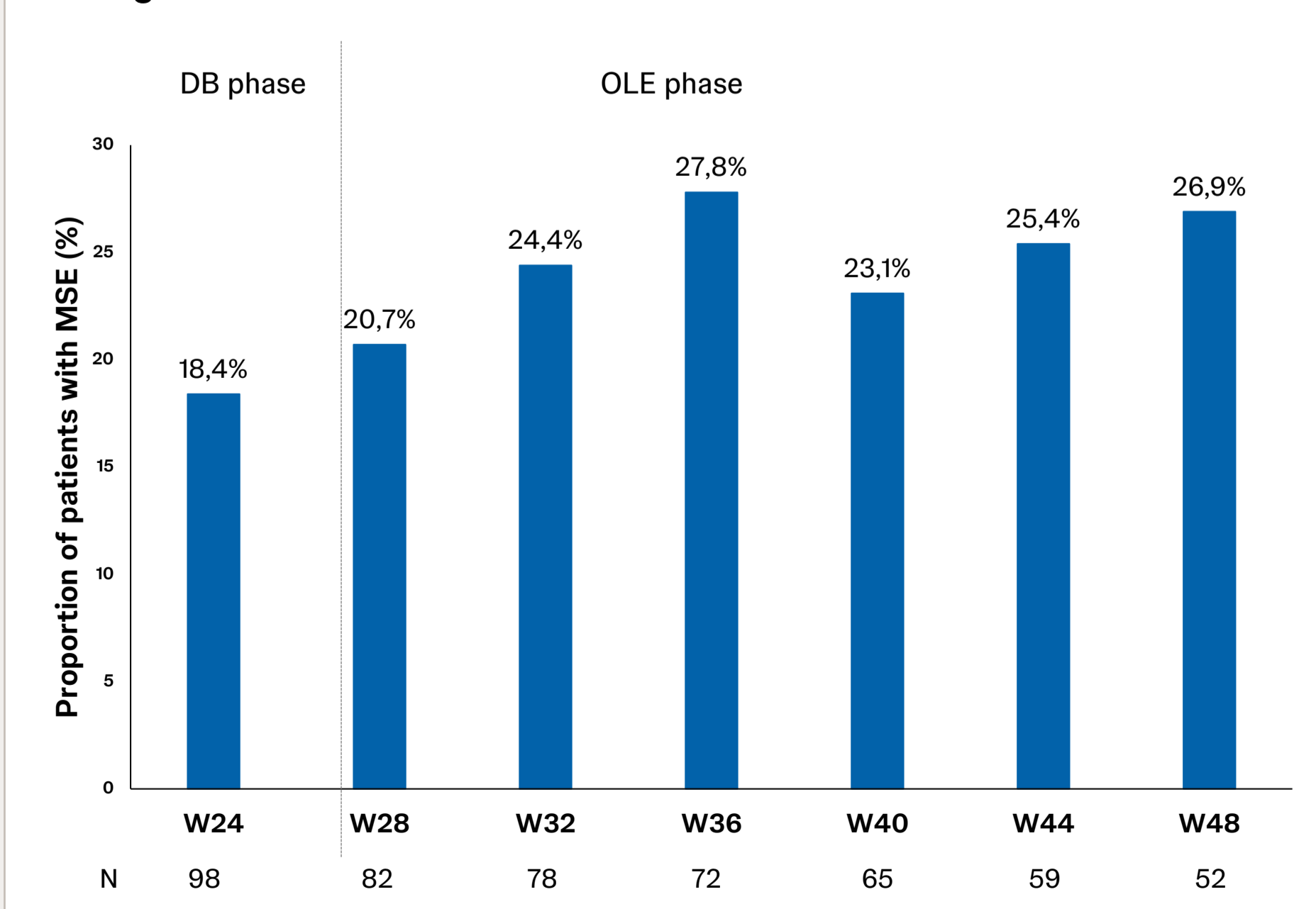


<sup>a</sup>Minimal clinical improvement is defined as MG-ADL total score improvement of at least 2 points from Open-label Phase baseline. <sup>b</sup>Percentage of time with improvement calculated as cumulative days of improvement divided by number of days in study up to OLE Week 24. The number of days in study up to OLE Week 24 is calculated as OLE Week 24 date (or early termination date if earlier) minus DB baseline date

### 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<sup>b</sup> 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<sup>a</sup> in MG-ADL score through week 48



<sup>a</sup>MSE is defined as MG-ADL total score of 0 or 1. <sup>b</sup>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.

## Conclusions

- ✓ Nipocalimab + SOC demonstrated significant and clinically meaningful efficacy **beyond the week 24** of double-blind phase
- ✓ Disease control of MG was prolonged during the OLE phase, demonstrating a **substantial and sustained efficacy** of nipocalimab in patients exposed **up to 48-weeks**
- ✓ These data reinforce results of a different analysis (that includes all the patients transitioned to OLE phase) showing that nipocalimab treatment results in **sustained, clinically meaningful disease control over 84 weeks** in a broad population of autoantibody-positive adults with gMG

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LEGEND:

CFB= change from baseline; CHMP= committee for medicinal products for human use; DB=double-blind; EMA= european medicine agency; FDA= food and drug administration; IV= Intravenous; MCI= meaningful clinical improvements; MG-ADL= Myasthenia Gravis-activities of daily living; MGFA= Myasthenia Gravis Foundation of America; MSE=minimal symptom expression; NIPO= nipocalimab; OLE= open-label extension; PBO= placebo; QoL= quality of life; QMG= quantitative Myasthenia Gravis; Q2W= every 2 weeks; R= randomized 1:1; SD= standard deviation; SE= standard error; SOC= standard-of-care; W=week; wks= weeks

These data were previously presented by Dr. Wim Noel at the 11th Congress of the European Academy of Neurology; June 21-24, 2025; Helsinki, Finland

## Acknowledgments

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## Disclosures

Giorgio M. Boggia is an employee of Johnson & Johnson

<sup>a</sup>All patients received the loading dose of nipocalimab 30 mg/kg at Week 0 and then started Nipocalimab 15 mg/kg Q2W IV from week 2 to week 24; <sup>b</sup>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; <sup>c</sup>In the EU, the OLE phase will be up to 240 wks; <sup>d</sup>Due to the COVID-19 pandemic, some participants from the Phase 2 study were unable to enter the Phase 2 OLE study. These participants could directly enter the Phase 3 OLE and their data will be disclosed later.