Efficacy of Nipocalimab in Adult Patients with Moderate-to-Severe Ocular Manifestations of Generalized Myasthenia Gravis in Phase 3 Vivacity-MG3 Study

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Affiliation at the time of study

Background

- In patients with generalized myasthenia gravis (gMG), 15–50% present with ocular manifestations (ptosis, diplopia).[1-3]
- Ocular symptoms in gMG limit daily activities (e.g., driving, reading) and significantly reduce quality-of-life.[4,5]
- Nipocalimab, as add-on to standard-of-care (SOC), demonstrated sustained efficacy versus placebo+SOC in a double-blind, 24-week, phase 3 study (Vivacity-MG3) in adult patients with gMG.[6]
- Nipocalimab, a neonatal fragment crystallizable (Fc) receptor-binding monoclonal antibody has been approved by the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) for the treatment of gMG in adult and pediatric patients (≥12 years) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.[7,8]

Objectives

This *post-hoc* analysis evaluated efficacy of nipocalimab vs placebo in the subgroup of patients with moderate-to-severe ocular manifestations (MSOM)

Methods

Eligibility criteria and efficacy analysis

- **Vivacity-MG3 inclusion criteria**
  - Age: ≥18 years.
  - The Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II a/b, III a/b, or IV a/b for gMG that was not well-controlled with stable MG therapy (or, who discontinued MG therapy due to intolerance or lack of efficacy).
  - Myasthenia Gravis-Activities of Daily Living (MG-ADL) scores ≥6 at screening and baseline.
- **Analysis population**
  - MSOM population was defined as baseline score of ≥2 points on either diplopia or ptosis items of MG-ADL scale.

Endpoints and assessments

- **Endpoints assessed**
  - Mean change from baseline (CFB) to week 24 in:
    - MG-ADL-ocular scores.
    - MG-ADL-total scores.
  - Proportion achieving meaningful within-person improvement (MWPI) of ≥2 points at 24-weeks from baseline.
- **Statistical methods**
  - Mean changes were compared using Wilcoxon signed-rank test; additionally, repeated measures models were utilized to analyze least squares (LS) mean CFB to week 24.
  - Chi-square test statistics evaluated proportion achieving MWPI.
  - Logistic regression models were used to examine likelihood (odds ratio [OR]) of achieving MWPI.

Key Takeaways

This *post-hoc* analysis in patients with gMG and MSOM suggests that:

- **Nipocalimab-treated patients showed significant improvements on the MG-ADL-ocular and MG-ADL-total scores vs placebo-treated-participants.**
- **Nipocalimab-treated patients were significantly more likely to achieve meaningful within person improvement in MG-ADL at week 24 than placebo-treated-participants.**

Results

Baseline and demographic characteristics

- At baseline, within MSOM subgroup, nipocalimab (n=54) and placebo (n=51) arms were comparable in mean age, BMI and mean (standard deviation [SD]) MG-ADL-ocular and MG-ADL-total scores (**Table 1**).

Table 1: Patient baseline and demographic characteristics

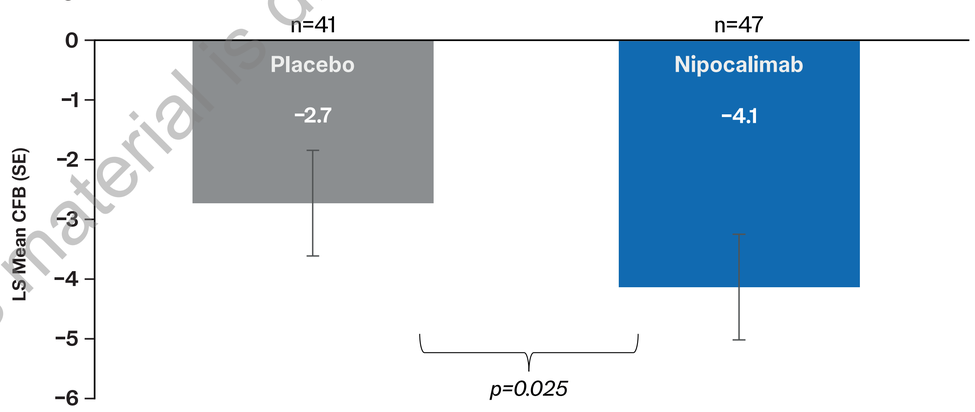
	Nipocalimab n=54	Placebo n=51
Age, mean (SD)	52.5 (15.59)	53.5 (16.77)
Female (%)	63	55
BMI, mean (SD)	27.6 (5.56)	29.2 (5.77)
Duration of MG (years), mean (SD)	7.3 (8.01)	9.2 (8.86)
MG-ADL-total, mean (SD)	10.1 (2.8)	9.5 (1.9)
MG-ADL-ocular, mean (SD)	4.1 (1.2)	3.5 (1.0)

BMI=Body mass index, **MG**=Myasthenia gravis, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SD**=Standard deviation.

MG-ADL-total scores with nipocalimab vs placebo

- At week 24, the change from baseline LS mean difference in MG-ADL total scores was significantly greater with nipocalimab vs placebo (**Figure 1**):
  - Mean difference (SE) MG-ADL-total for nipocalimab vs placebo: −1.35 (0.680); p=0.025.

Figure 1: Change from baseline at week 24 in MG-ADL-total score

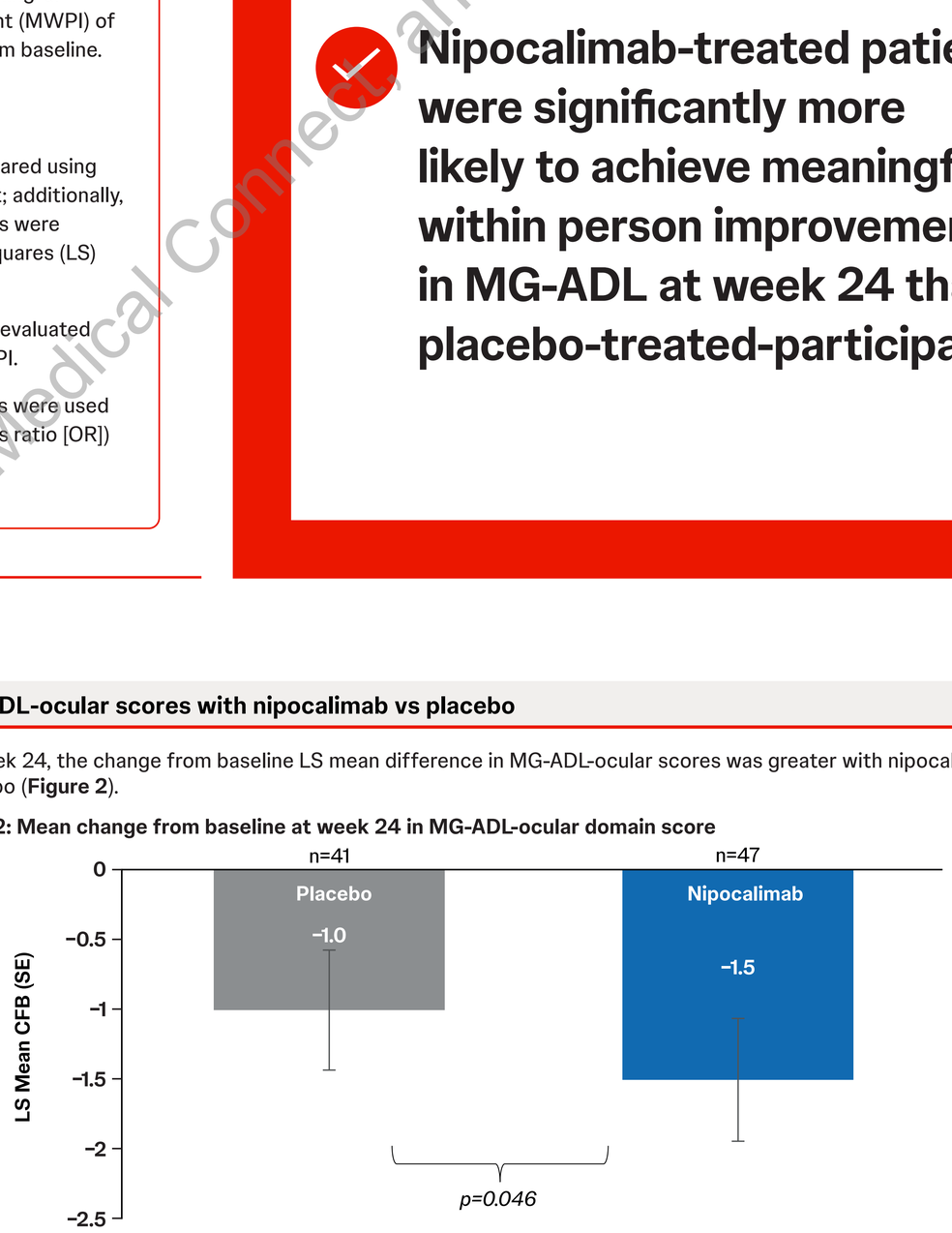


p values were calculated using Wilcoxon signed-rank test; **CFB**=Change from baseline, **LS**=Least squares, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SE**=Standard error.

MG-ADL-ocular scores with nipocalimab vs placebo

- At week 24, the change from baseline LS mean difference in MG-ADL-ocular scores was greater with nipocalimab vs placebo (**Figure 2**).

Figure 2: Mean change from baseline at week 24 in MG-ADL-ocular domain score

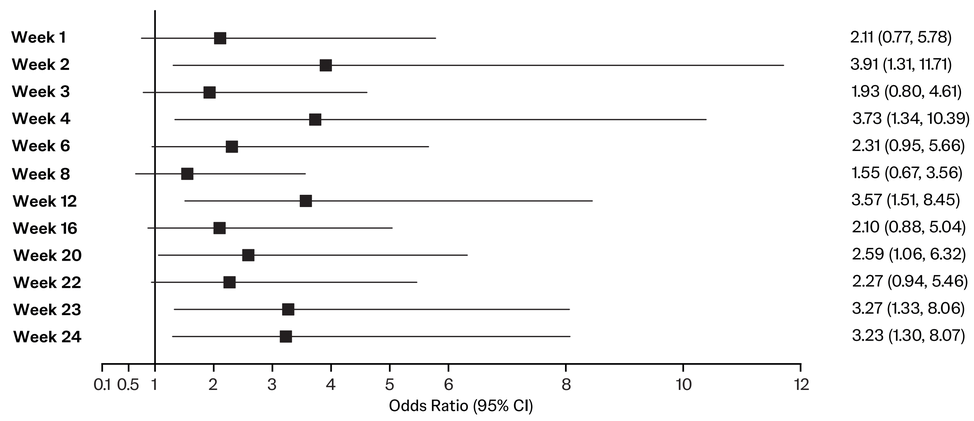


p values were calculated using Wilcoxon signed-rank test; **CFB**=Change from baseline, **LS**=Least squares, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SE**=Standard error.

MG-ADL-ocular likelihood of achieving MWPI (≥2 point improvement) at week 24

- Significantly greater proportion of participants achieved meaningful within person improvement at week 24 on MG-ADL-ocular domain with nipocalimab than placebo (51% vs 24%); odds ratio (95% CI): 3.23 (1.30, 8.07) (**Figure 3**).

Figure 3: Odds of achieving MWPI in MG-ADL-ocular domain score



CI=Confidence interval, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MWPI**=Minimum within person improvement.

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