EPR 306

Efficacy of Nipocalimab in Adult Patients with Moderate-to-severe Ocular Manifestations of gMG in Phase 3 VIVACITY-MG3

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DISCLOSURES

Kristl Claeys: Speaker/advisory board honoraria: Alexion, Alnylam, Amicus Therapeutics, ArgenX, AstraZeneca, Biogen, Edgewise, Ipsen, Janssen Pharmaceuticals, Lupin, Pfizer, Roche, Sanofi-Genzyme, UCB and research funding from Alnylam, Biogen, CSL Behring, Roche, Vertex, Sanofi-Genzyme.

Kavita Gandhi, Ibrahim Turkoz, Sheryl Pease, Charlotte Gary, Zia Choudhry, and **Sindhu Ramchandren:** Employees of Johnson & Johnson, may hold stocks/stock options in Johnson & Johnson.

Maria Ait-Tihyaty: Employee of Johnson & Johnson at the time of study. Currently employed at Dianthus Therapeutics, Inc.

INTRODUCTION AND OBJECTIVE

- In gMG, 15–50% of patients present with ocular manifestations (ptosis, diplopia)[1]
- Ocular symptoms in gMG limit daily activities (e.g., driving, reading) and significantly reduce quality-of-life[2]
- Nipocalimab, as add-on to SOC, demonstrated sustained efficacy versus placebo+SOC in a double-blind, 24-week, phase 3 study (VIVACITY-MG3) in adult patients with gMG[3]
- Nipocalimab, a neonatal Fc receptor-binding monoclonal antibody has been approved by the US FDA for the treatment of gMG in adult and pediatric patients (≥12 years) who are anti-AChR or anti-MuSK antibody positive[4]

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

[1]Silvestri, N. J., & Wolfe, G. I. (2022). *Neurologic Clinics,* 40(2), 261–274; [2]Farmakidis, C., et al. (2020). *Current Opinion in Neurology* 33(5), 663–671; [3]Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105-116; [4]Nipocalimab US PI available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761430s000lbl.pdf (last accessed date 20 May 2025).
AChR=anti-acetylcholine receptor; Fc= fragment crystallizable; FDA=Food and Drug Administration; gMG=generalised myasthenia gravis; MuSK=anti-muscle-specific tyrosine kinase; SOC=standard-of-care

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METHODS

Eligibility criteria and efficacy analysis

- **VIVACITY inclusion criteria**
  - ≥18 years
  - 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)
  - MG-ADL scores ≥6 at screening and baseline
- **Analysis population**
  - Moderate-to-severe ocular manifestation (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 W24 in:
  - MG-ADL-ocular scores
  - MG-ADL-total scores
- **Statistical methods**
  - Mean changes were compared using Wilcoxon signed-rank test, additionally, repeated measures models were utilized to analyze LS mean CFB to W24
  - Chi-square test statistics evaluated proportion of patients achieving MWPI of ≥2-points at 24-weeks from baseline
  - Logistic regression models were used to examine likelihood (OR) of achieving MWPI

gMG=generalized myasthenia gravis; LS=least squares; MG-ADL=Myasthenia Gravis-Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; MWPI=meaningful within-person improvement; OR=odds ratio; W=week

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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 (SD) MG-ADL-ocular and MG-ADL-total scores

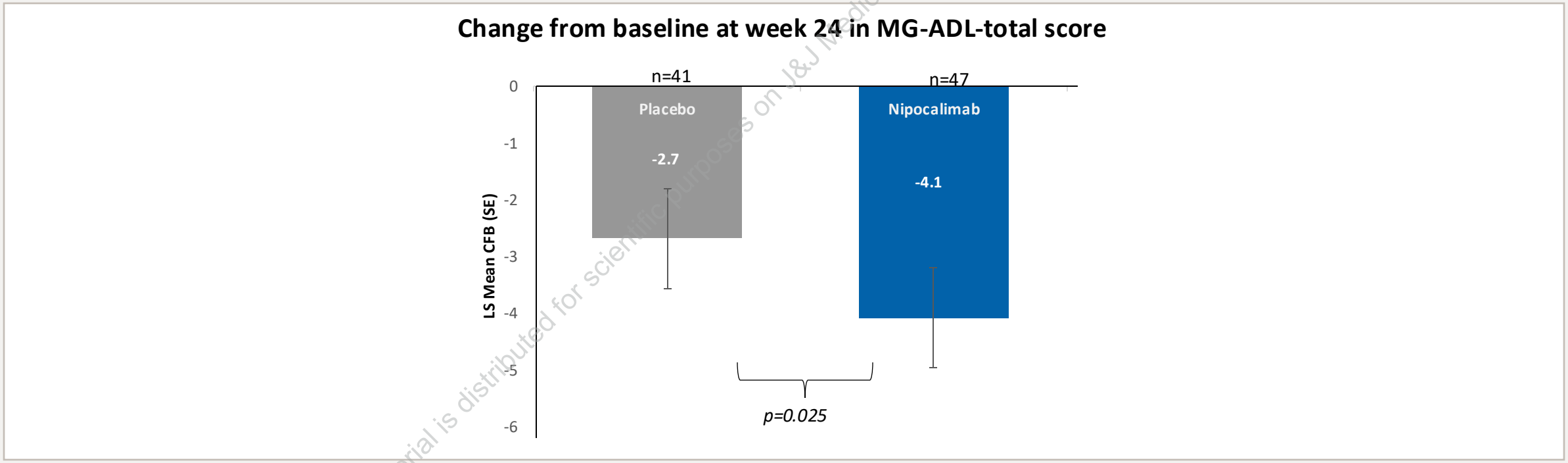
	Nipocalimab n=54	Placebo n=51
Age, mean (SD)	52.5 (15.59)	53.5 (16.77)
Female (%)	63	55
BMI Mean (SD)	27.6 (5.56)	29.2 (5.77)
Duration of MG (years), mean (SD)	7.3 (8.01)	9.2 (8.86)
MG-ADL-total, mean (SD)	10.1 (2.8)	9.5 (1.9)
MG-ADL-ocular, mean (SD)	4.1 (1.2)	3.5 (1.0)

AchR=acetylcholine receptor; BMI=body mass index; MG=myasthenia gravis; MG-ADL=Myasthenia Gravis-Activities of Daily Living; MSOM=moderate-to-severe ocular manifestations; MuSK=muscle-specific kinase; MWPI=meaningful within-person improvement; SD=standard deviation

RESULTS – 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:

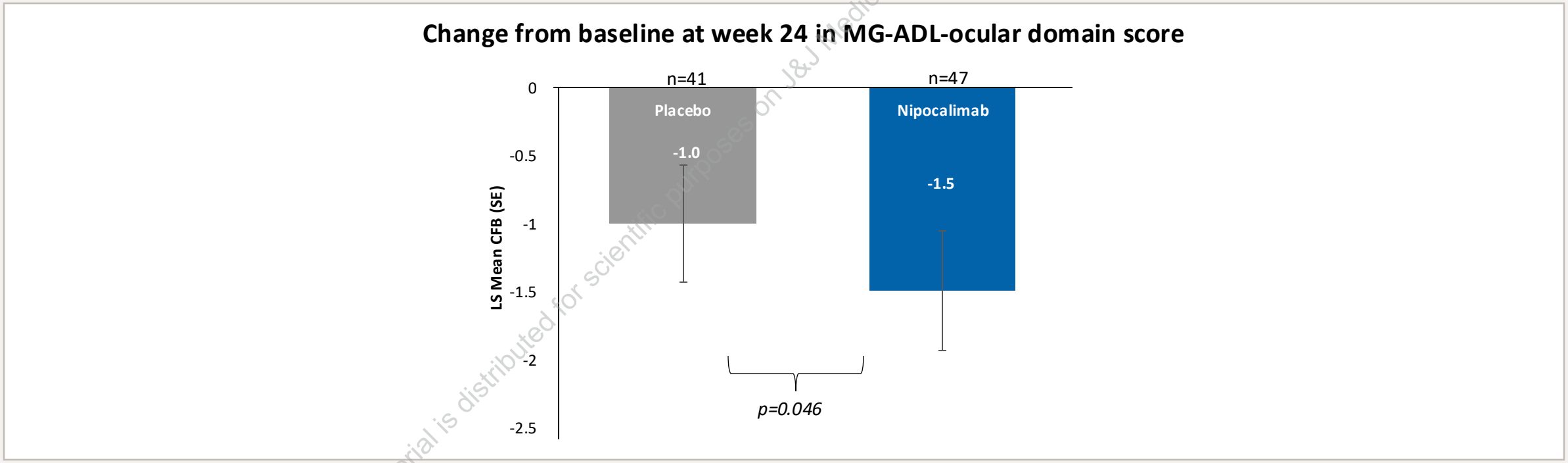
- Mean difference (SE) MG-ADL-total for nipocalimab vs placebo: −1.35 (0.680); *p=0.025*



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; OR=odds ratio

RESULTS – MG-ADL-ocular scores with nipocalimab vs placebo

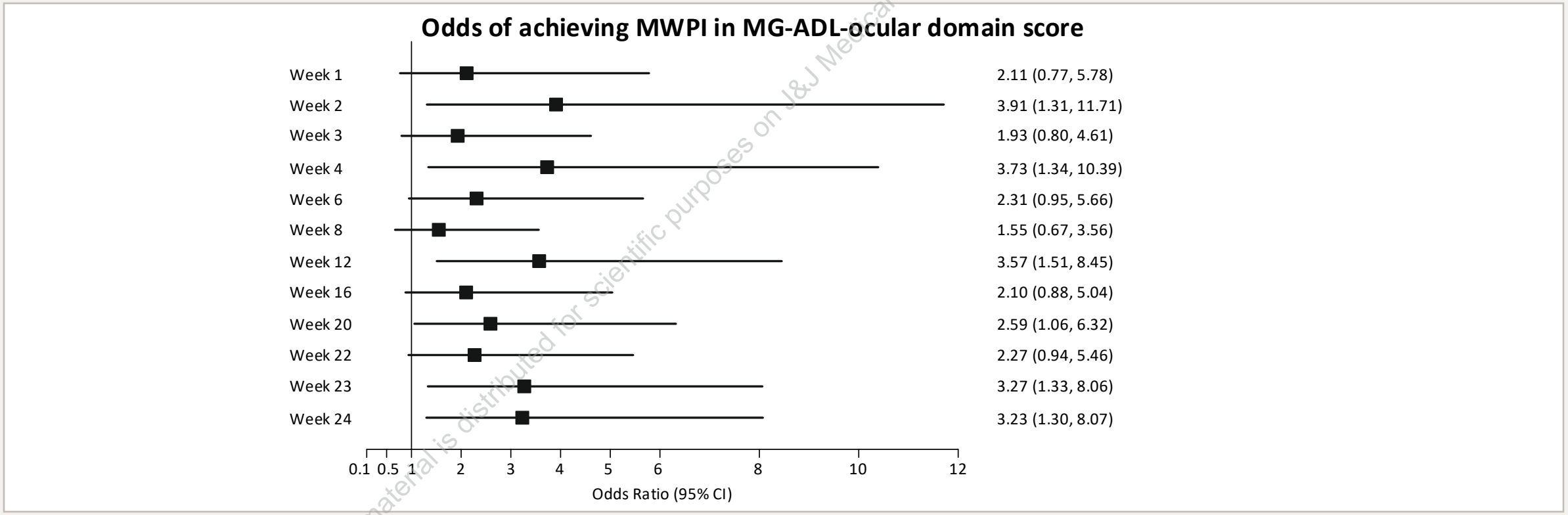
At week 24, the change from baseline LS mean difference in MG-ADL-ocular scores was greater with nipocalimab vs placebo



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; OR=odds ratio

RESULTS – 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 (CI): 3.23 (1.30, 8.07)



CI=confidence interval; MG-ADL=Myasthenia Gravis-Activities of Daily Living; MSOM= moderate-to-severe ocular manifestations; MWPI=minimum within person improvement

CONCLUSIONS

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

gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis-Activities of Daily Living; MSOM=moderate-to-severe ocular manifestations