Composite Response to Nipocalimab Based on Both Myasthenia Gravis Activity of Daily Living and Quantitative Myasthenia Gravis Scores in Patients with Generalized Myasthenia Gravis

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Key Takeaways

- **This post-hoc analysis evaluated composite response based on ability to achieve a 2-point meaningful improvement on the MG-ADL scale and a 3-point meaningful improvement on the QMG scale over a 24-week double-blind study period.**
- **Nipocalimab + SOC treatment resulted in a significantly greater proportion of patients achieving composite response compared with placebo + SOC during the trial.**
- **Patients treated with nipocalimab + SOC were at least 4 times more likely to sustain composite response over 20 weeks compared to patients treated with placebo + SOC.**

Background

- Myasthenia gravis (MG), a rare autoimmune neuromuscular disease, is characterized by fatigability and muscle weakness, with a significant negative impact on a patient's quality of life.[1,2]
- Nipocalimab, a neonatal Fc receptor blocker, demonstrated statistically significant efficacy versus placebo with the MG activities of daily living (MG-ADL) and quantitative MG (QMG) scales in the 24-week double-blind Phase-3 Vivacity-MG3 study (NCT04951622).[3]
  - Least-squares mean (SE) change in MG-ADL score from baseline to Week 22, 23 and 24: –4.70 (0.329) for nipocalimab + SOC vs –3.25 (0.335) for placebo + SOC (difference –1.45 [95% CI: –2.38 to –0.52]; p=0.002).
  - Least-squares mean (SE) change in QMG from baseline to Week 22 and 24: –4.86 (0.504) for nipocalimab + SOC vs –2.05 (0.499) for placebo + SOC (difference –2.81 [95% CI: –4.22 to –1·41]; p<0.001.
- MG-ADL entails patient recall of symptoms, and QMG physician assessment of treatment response. Therefore, combining the two can provide valuable insights on treatment response that reflects both perspectives.

Objective

- **The aim of this analysis was to evaluate the likelihood of composite treatment response using the MG-ADL and QMG scales, representing the patient's and the clinician's perspectives, respectively, in patients with generalized MG (gMG) receiving nipocalimab + SOC or placebo + SOC.**

Methods

- Composite response was defined as having MG-ADL total score improvement of ≥2 points and QMG total score improvement of ≥3 points from baseline. The proportion of patients achieving composite response was assessed at each visit.
- The differences in the proportion of patients achieving a composite response by week were assessed using stratified Cochran-Mantel-Haenszel tests or Fisher's exact tests. Odds ratios (OR) were calculated using logistic regression models.
- The proportion of patients with sustained composite response for ≥8, 12, 16 and 20 weeks was examined. Patients with missing change in MG-ADL and/or QMG were considered as not having met improvement criteria.
- To evaluate the likelihood of achieving composite response rates and the differences over a 24-week period, generalized estimating equations were employed to account for within-patient correlations across visits.

Results

Baseline characteristics

- Patients had a mean age of 52.4 years, were mostly women (60.1%), and had a mean MG-ADL total score of 9.2 and a mean QMG total score of 15.4 (**Table 1**).

Table 1: Demographics and baseline characteristics

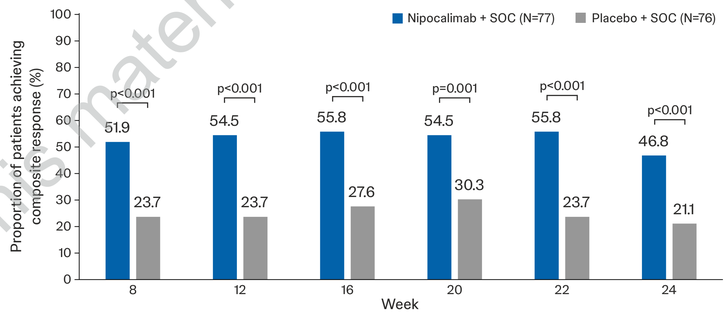
Characteristics	Nipocalimab + SOC (n=77)	Placebo + SOC (n=76)	Total (N=153)
Age, years, mean (SD)	52.5 (15.7)	52.3 (16.4)	52.4 (16.0)
Race, n (%)			
White	49 (63.6)	47 (61.8)	96 (62.7)
Asian	24 (31.2)	25 (32.9)	49 (32.0)
Sex, women, n (%)	50 (64.9)	42 (55.3)	92 (60.1)
MG-ADL total score, mean (SD)	9.4 (2.7)	9.0 (2.0)	9.2 (2.4)
QMG total score, mean (SD)	15.1 (4.8)	15.7 (4.9)	15.4 (4.9)
Duration of gMG, years, mean (SD)	6.9 (7.4)	8.9 (8.1)	7.9 (7.8)
Age at onset of gMG, years, mean (SD)	45.1 (17.3)	42.6 (18.7)	43.8 (18.0)
Autoantibody status at screening			
Seropositive	77 (100.0)	76 (100.0)	153 (100.0)
Anti-AChR+, n (%)	63 (81.8)	71 (93.4)	134 (87.6)
Anti-MuSK+, n (%)	12 (15.6)	4 (5.3)	16 (10.5)
Anti-LRP4+, n (%)	2 (2.6)	1 (1.3)	3 (2.0)

AChR=Acetylcholine receptor, **gMG**=Generalized myasthenia gravis, **LRP4**=Low-density lipoprotein receptor 4, **MG-ADL**=Myasthenia gravis-activities of daily living, **MuSK**=Muscle-specific tyrosine kinase, **QMG**=Quantitative myasthenia gravis, **SD**=Standard deviation, **SOC**=Standard of care.

Composite response by week

- At Week 24, 46.8% of nipocalimab-treated versus 21.1% of placebo-treated patients achieved composite response (**Figure 1**).

Figure 1: Proportion of patients achieving composite response by week

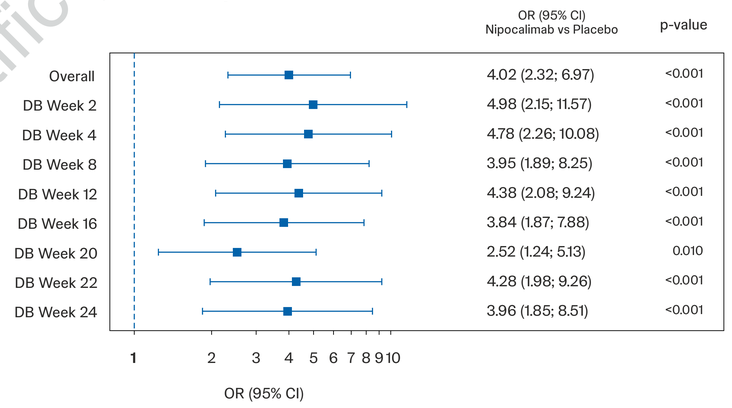


Participants with missing change scores in the MG-ADL and/or QMG total score were considered as not having met the composite improvement criteria. **MG-ADL**=Myasthenia gravis-activities of daily living, **QMG**=Quantitative myasthenia gravis, **SOC**=Standard of care.

Likelihood of achieving composite response

- Nipocalimab-treated patients were 4 times more likely to achieve composite response (OR: 4.02 [95% CI]: 2.32, 6.97) over 24 weeks (**Figure 2**).

Figure 2: Likelihood of achieving composite response over the 24-week treatment period

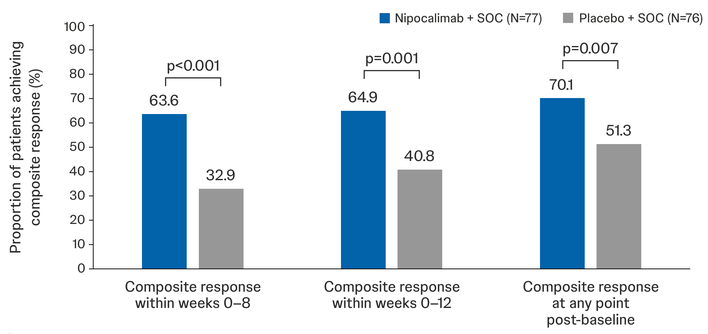


CI=Confidence interval, **DB**=Double-blinded, **OR**=Odds Ratio.

Proportion of patients achieving composite response over time

- The proportion of patients achieving composite response within the first 8 weeks with nipocalimab was twice more than placebo-treated patients (OR: 3.86 [1.93, 7.72], p<0.001) (**Figure 3**).

Figure 3: Proportion of patients achieving composite response over time

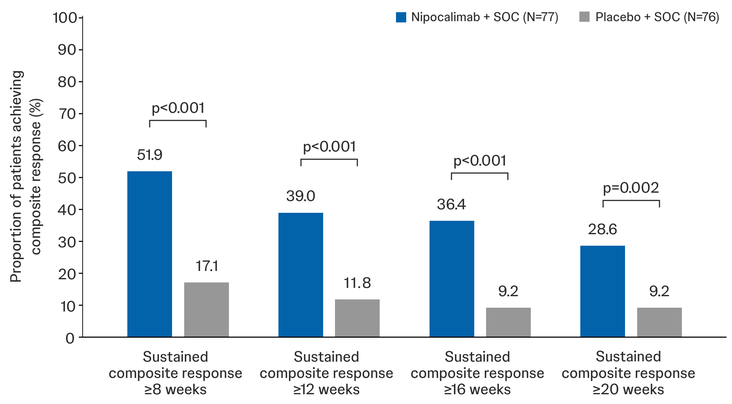


SOC=Standard of care.

Duration of sustained composite response

- The proportion of nipocalimab-treated patients was 2–4 times greater than placebo-treated patients in sustaining a composite response for 6 weeks or longer (**Figure 4**).

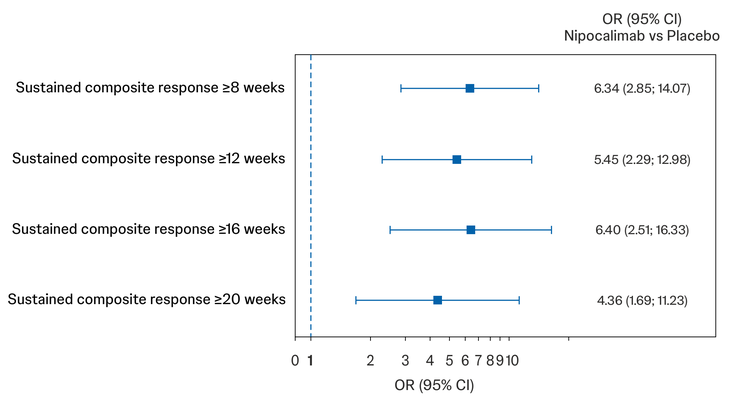
Figure 4: Duration of sustained composite response



SOC=Standard of care.

- Nipocalimab-treated patients were at least 4 times more likely to achieve sustained composite response for ≥8, 12, 16 and 20 weeks versus placebo (**Figure 5**).

Figure 5: Likelihood of sustained composite response



CI=Confidence interval, **OR**=Odds Ratio.

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