Predictors of Composite Response in Myasthenia Gravis Based on Patient and Clinician-Reported Assessments—In Vivacity-MG3 Phase 3 Trial

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Key Takeaways

- **In this post-hoc analyses of CR that evaluated ability to achieve meaningful improvement on both the MG-ADL and QMG:**
  - **Significantly greater proportion of nipocalimab-treated patients achieved CR at Week 24 than placebo-treated patients.**
  - **Nipocalimab-treated patients were 4 times more likely to achieve CR than placebo-treated patients over 24 weeks.**
  - **Independent of treatment, early response and higher (worse) baseline bulbar and limb weakness scores on the QMG were important predictors of achieving CR highlighting opportunity for focused treatment goals.**

Background

- Generalised myasthenia gravis (gMG) is a rare chronic neuromuscular disorder characterised by muscle weakness.[1]
- Nipocalimab, as add-on to standard-of-care (SOC), demonstrated stable and sustained efficacy versus placebo+SOC in a double-blind, 24-week, phase 3 study (Vivacity-MG3) in adult patients with gMG.[1]
  - Based on these findings, nipocalimab was recently granted United States Food and Drug Administration approval for treating adult and paediatric patients (≥12 years) with gMG who are positive for anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibodies. Committee for Medicinal Products for Human Use has also adopted a positive opinion, recommending the granting of marketing authorization in European Union.[2]
  - Myasthenia gravis-Activities of daily living (MG-ADL) is a patient reported scale while quantitative MG (QMG) is physician assessed scale; combining both provides comprehensive insights from both physician and patient's perspective on muscle function.[3]
  - The inclusion of both the MG-ADL and QMG endpoints to determine composite responders at Week 24 allows a comprehensive evaluation of how patients with gMG feel, function, and cope with their disease.

Objective

- **To identify predictors of composite response (CR) with nipocalimab+SOC versus placebo+SOC among patients with gMG from the Vivacity-MG3 study.**

Methods

- Composite response was defined as clinically meaningful improvements from baseline of ≥2-points in MG-ADL and ≥3-points in QMG total scores.
- Generalised estimating equations were used to analyse odds of achieving CR over 24 weeks.
- A post-hoc exploratory approach identified predictors of CR at Week 24 using univariate and multivariate regression models; in line with a post-hoc analysis with nominal significance defined as $p<0.05$ and no adjustment made for multiplicity.
- Given the observed heterogeneity in the presentation, history, and prognosis of gMG, it is unlikely that any single variable in isolation would have clinically useful predictive utility; therefore, stepwise multiple logistic regression models identified potential patient characteristics associated with CR.
- Predictors were entered sequentially, and after entering the variables in the model, those that became nonsignificant were checked and removed from the model (entry $p\leq0.1$ and stay $p\leq0.1$). Odds ratios (OR) and 95% confidence interval (CI) were calculated. Both p values and ORs are reported.
- Variable selection approaches based on random forest models were also performed.

Results

- Baseline characteristics were similar among patients in both treatment groups (**Table 1**).

Table 1: Baseline demographics and characteristics

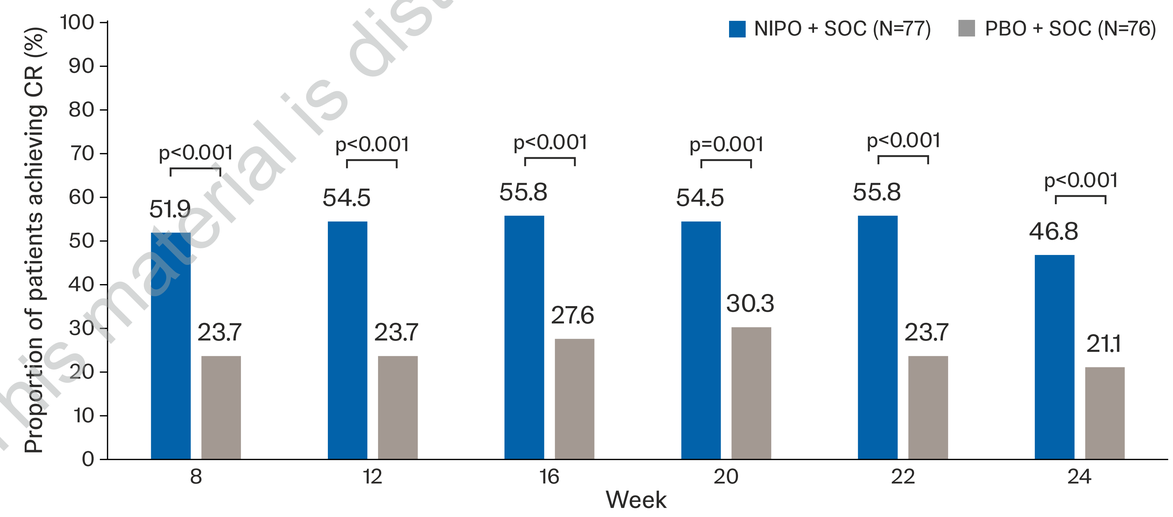
	NIPO + SOC n=77	PBO + SOC n=76
Age, mean (range), years	52.5 (20, 81)	52.3 (20, 81)
Female, n (%)	50 (64.9%)	42 (55.3%)
Race, n (%)		
American Indian or Alaska native	1 (1.3%)	0
Asian	24 (31.2%)	25 (32.9%)
Black/African American	1 (1.3%)	1 (1.3%)
White	49 (63.6%)	47 (61.8%)
Not reported	2 (2.6%)	3 (3.9%)
BMI, mean (SD), kg/m^2	27.6 (5.39)	28.5 (5.78)
Baseline MG-ADL total score, mean (SD)	9.4 (2.73)	9.0 (1.97)
Baseline QMG total score, mean (SD)	15.1 (4.78)	15.7 (4.92)
Anti-AChR$^+$/Anti-MuSK$^+$/Anti-LRP4$^+$, n	63/12/2	71/4/1

AChR$^+$=Acetylcholine receptor antibody-positive; **BMI**=Body mass index; **LRP4**$^+$=Low density lipoprotein receptor-related protein 4-positive; **MG-ADL**=Myasthenia gravis-Activities of daily living; **MuSK**$^+$=Muscle-specific kinase antibody-positive; **NIPO**=Nipocalimab; **PBO**=Placebo; **QMG**=Quantitative Myasthenia Gravis; **SD**=Standard deviation; **SOC**=Standard-of-care.

CR by week

- Significantly higher proportion of nipocalimab-treated patients achieved CR than placebo treated patients across all time points ($p<0.001$; **Figure 1**).

Figure 1: Proportion of patients achieving CR by week

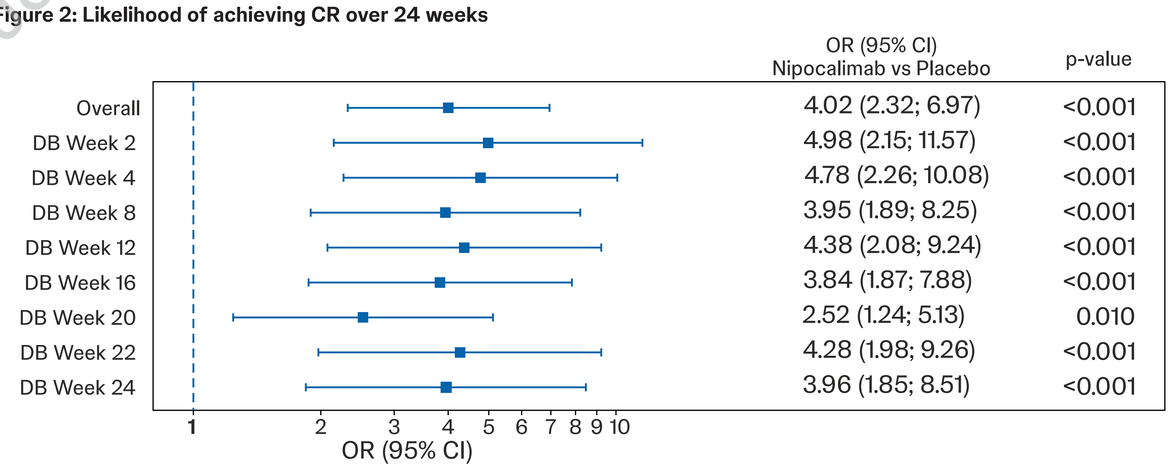


CR=Composite response; **NIPO**=Nipocalimab; **PBO**=Placebo; **SOC**=Standard-of-care.

Likelihood of achieving CR

- At Week 2, nipocalimab-group patients had nearly 5.0-fold (95% CI: 2.15–11.57) greater odds of achieving CR vs placebo-group patients and at Week 24, they had nearly 4.0-fold (95% CI: 1.85–8.51) greater odds (**Figure 2**) of achieving CR.

Figure 2: Likelihood of achieving CR over 24 weeks



CI=Confidence interval; **CR**=Composite response; **DB**=Double blind; **OR**=Odds ratio.

Predictors of CR

- Initial univariate logistic regression models identified potential parameters associated with response (**Table 2A**).

Table 2A: Univariate model

Predictors	OR (95% CI)	p-value
Treatment, NIPO vs PBO	3.21 (1.53–6.70)	0.002
Baseline MG-ADL Domain: Bulbar	1.28 (1.01–1.63)	0.039
Baseline MG-ADL Domain: Limb Weakness	1.37 (1.00–1.87)	0.047
Baseline QMG Total Score	1.11 (1.03–1.20)	0.008
Baseline QMG Domain: Bulbar	1.42 (1.07–1.87)	0.014
Baseline QMG Domain: Limb Weakness	1.13 (1.01–1.26)	0.032
Early Response (Week 2), Yes vs No	9.56 (3.83–23.90)	<0.001

- From multiple regression model and independent of treatment group, early response and higher (worse) baseline bulbar and limb weakness scores on the QMG were significant predictors of achieving CR (**Table 2B**).

Table 2B: Multiple regression model

Predictors stayed in the final model	OR (95% CI)	p-value
Treatment, NIPO vs PBO	2.82 (1.15–6.90)	0.023
Baseline QMG Domain: Bulbar	1.52 (1.08–2.14)	0.016
Baseline QMG Domain: Limb Weakness	1.70 (1.12–2.56)	0.012
Early Response (Week 2), Yes vs No	7.40 (2.71–20.23)	<0.001

Note: Response is defined as having MG-ADL total change of ≤2 and QMG total change of ≤3 at Week 24. Seven subjects who had MG-ADL total change and missed QMG total change scores at Week 24 are considered as non-responders. Early response (Week 2) is defined as having MG-ADL total change of ≤2 and QMG total change of ≤3 at Week 2. **CI**=Confidence interval; **MG-ADL**=Myasthenia gravis-Activities of daily living; **NIPO**=Nipocalimab; **OR**=Odds ratio; **PBO**=Placebo; **QMG**=Quantitative Myasthenia Gravis.

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