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Quality of Life in Generalized Myasthenia Gravis Patients Achieving Sustained Versus Transient Clinical Outcomes in the Phase 3 Vivacity-MG3 Trial

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Key Takeaways

- **In this Vivacity-MG3 post-hoc analysis, nipocalimab-treated participants with gMG were more likely to achieve and sustain CR for ≥8 weeks compared with those receiving placebo**
- **Participants achieving sustained versus transient CR or MCI demonstrated greater improvements in HRQoL and fatigue scores**
- **These findings suggest that ≥8-week sustained outcomes deliver clinically relevant HRQoL benefits and should be considered important patient-centered treatment goals for patients with gMG receiving advanced treatments**

Background

Generalized myasthenia gravis (gMG) is a chronic, immunoglobulin G autoantibody-mediated autoimmune neuromuscular disease associated with unpredictable, fluctuating muscle weakness[1,2]

In the phase 3 Vivacity-MG3 study, participants with gMG who received nipocalimab demonstrated improved and sustained efficacy versus those receiving placebo[3]

Minimal clinically important improvement (MCI) in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score (≥2-point improvement)[4] or a composite response (CR) of ≥2-point improvement in MG-ADL and ≥3-point improvement in Quantitative Myasthenia Gravis scores are plausible treatment goals in gMG[5]

- Examining whether patients achieve sustained MCI or CR is important because these endpoints indicate durable symptom relief and functional improvement that can boost patient quality of life, reduce caregiver burden, and give clinicians actionable evidence to guide treatment and long-term management

Objective

To evaluate health-related quality of life (HRQoL) in participants with gMG achieving sustained versus transient MCI or CR in Vivacity-MG3

Methods

Participants

- This post-hoc analysis of Vivacity-MG3 (NCT04951622) included participants in the prespecified efficacy analysis population
  - Randomized participants who received at least one dose of study drug (nipocalimab or placebo) in the double-blind phase and were antibody positive for a gMG-related pathogenic antibody (anti-acetylcholine receptor, anti–muscle-specific kinase, or anti–lipoprotein-related protein receptor 4)
- Nipocalimab- and placebo-treated participants were combined and then stratified into groups based on MCI or CR status over 24 weeks in the double-blind phase:
  - Never achieved MCI or CR (No MCI or CR)
  - Achieved MCI or CR sustained for ≥8 weeks (sustained MCI or CR)
  - Achieved MCI or CR at least once not sustained for ≥8 weeks (transient MCI or CR)

Assessments

- The proportion of participants achieving and sustaining MCI or CR was evaluated for nipocalimab versus placebo
- Logistic regression models compared likelihood (odds ratio) of achieving transient or sustained MCI or CR (reference = no MCI or CR) for nipocalimab versus placebo
- Treatment groups were combined, stratified by MCI or CR status, and then the impact of MCI or CR status on HRQoL was evaluated
  - Least squares mean change from baseline to week 24 was compared across MCI and CR groups using the Myasthenia Gravis Quality of Life 15-item revised instrument, Quality of Life in Neurological Disorders Fatigue Scale, and EuroQol-5-Dimension-5-Level visual analog scale
  - Between-group comparisons were made using analysis of covariance models at week 24 with fixed effects for group, autoantibody status, and region, and corresponding baseline scores as covariates

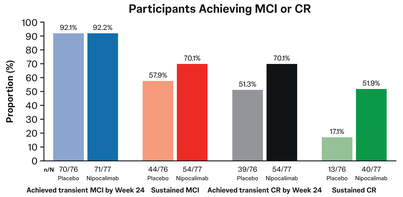
Results

Table 1. ***Baseline participant characteristics***

Characteristic	Nipocalimab + SOC (n=77)	Placebo + SOC (n=76)
Age, years, mean (SD)	52.5 (15.66)	52.3 (16.37)
Sex, female, n (%)	50 (64.9)	42 (55.3)
MG-ADL total score, mean (SD)	9.4 (2.73)	9.0 (1.97)
QMG total score, mean (SD)	15.1 (4.78)	15.7 (4.92)
MG-QOL15r total score, mean (SD)	16.9 (6.08)	15.5 (6.01)
Neuro-QoL Fatigue score, mean (SD)	59.5 (15.65)	55.3 (15.17)
EQ-VAS score, mean (SD)	54.7 (19.65)	57.8 (18.30)
Antibody positive at screening, n (%)		
AChR	63 (81.8)	71 (93.4)
MuSK	12 (15.6)	4 (5.3)
LRP4	2 (2.6)	1 (1.3)

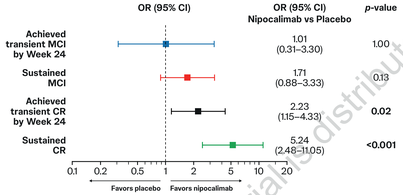
*AChR=acetylcholine receptor, **EQ-VAS**=EuroQol-5-Dimension-5-Level visual analog scale, **LRP4**=lipoprotein-related protein receptor 4, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **MG-QOL15r**=Myasthenia Gravis Quality of Life 15-item revised, **MuSK**=muscle-specific kinase, **Neuro-QoL Fatigue**=Quality of Life in Neurological Disorders Fatigue, **QMG**=Quantitative Myasthenia Gravis, **SD**=standard deviation, **SOC**=standard of care.*

Figure 1. ***Proportions of participants in each treatment group who achieved transient MCI or CR by week 24 and ≥8-week sustained MCI or CR***



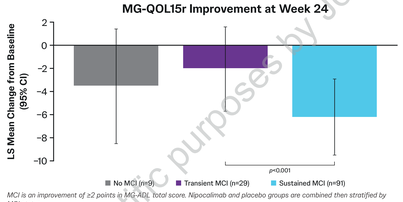
MCI is an improvement of ≥2 points in MG-ADL total score. CR is an improvement of ≥2 points in MG-ADL total score and ≥3 points in QMG score.
***CR**=composite response, **MCI**=minimal clinically important improvement, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **QMG**=Quantitative Myasthenia Gravis.*

Figure 2. ***Nipocalimab-treated participants were significantly more likely to achieve and sustain CR versus placebo-treated participants***



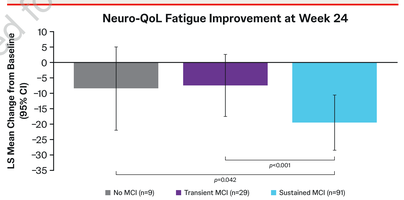
MCI is an improvement of ≥2 points in MG-ADL total score. CR is an improvement of ≥2 points in MG-ADL total score and ≥3 points in QMG score. p-values are from Fisher's exact test.
***CI**=confidence interval, **CR**=composite response, **MCI**=minimal clinically important improvement, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **OR**=odds ratio, **QMG**=Quantitative Myasthenia Gravis.*

Figure 3. ***Participants with sustained MCI demonstrated significantly greater improvements in MG-QOL15r versus those with transient MCI***



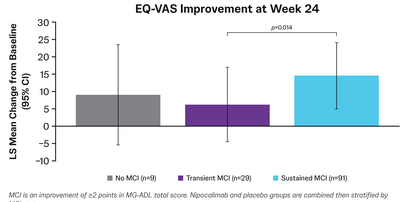
MCI is an improvement of ≥2 points in MG-ADL total score. Nipocalimab and placebo groups are combined then stratified by MCI status.
***CI**=confidence interval, **LS**=least squares, **MCI**=minimal clinically important improvement, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **MG-QOL15r**=Myasthenia Gravis Quality of Life 15-item revised.*

Figure 4. ***Participants with sustained MCI demonstrated significantly greater improvements in Neuro-QoL Fatigue versus those with transient MCI and no MCI***



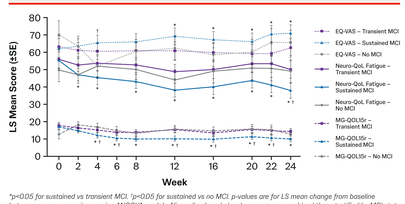
MCI is an improvement of ≥2 points in MG-ADL total score. Nipocalimab and placebo groups are combined then stratified by MCI status.
***CI**=confidence interval, **LS**=least squares, **MCI**=minimal clinically important improvement, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **Neuro-QoL Fatigue**=Quality of Life in Neurological Disorders Fatigue.*

Figure 5. ***Participants with sustained MCI demonstrated significantly greater improvements in EQ-VAS versus those with transient MCI***



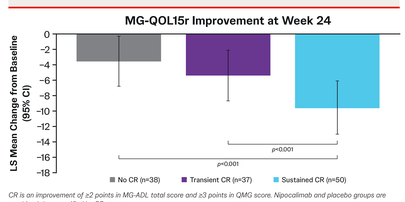
MCI is an improvement of ≥2 points in MG-ADL total score. Nipocalimab and placebo groups are combined then stratified by MCI status.
***CI**=confidence interval, **EQ-VAS**=EuroQol-5-Dimension-5-Level visual analog scale, **LS**=least squares, **MCI**=minimal clinically important improvement, **MG-ADL**=Myasthenia Gravis Activities of Daily Living.*

Figure 6. ***Significantly greater improvements in MG-QOL15r and Neuro-QoL Fatigue were demonstrated in participants achieving sustained MCI at week 2 and maintained through week 24***



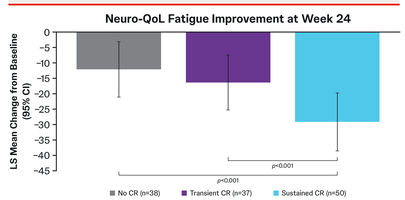
**p<0.05 for sustained vs transient MCI. †p<0.05 for sustained vs no MCI. p-values are for LS mean change from baseline between-group comparisons using ANCOVA models. Nipocalimab and placebo groups are combined then stratified by MCI status.*
***ANCOVA**=analysis of covariance, **EQ-VAS**=EuroQol-5-Dimension-5-Level visual analog scale, **LS**=least squares, **MCI**=minimal clinically important improvement, **MG-QOL15r**=Myasthenia Gravis Quality of Life 15-item revised, **Neuro-QoL Fatigue**=Quality of Life in Neurological Disorders Fatigue, **SE**=standard error.*

Figure 7. ***Participants with sustained CR demonstrated significantly greater improvements in MG-QOL15r versus those with transient CR and no CR***



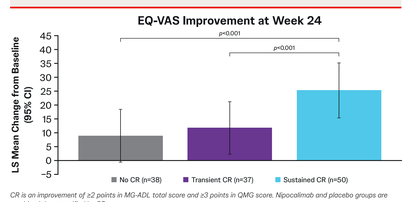
CR is an improvement of ≥2 points in MG-ADL total score and ≥3 points in QMG score. Nipocalimab and placebo groups are combined then stratified by CR status.
***CI**=confidence interval, **CR**=composite response, **LS**=least squares, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **MG-QOL15r**=Myasthenia Gravis Quality of Life 15-item revised, **QMG**=Quantitative Myasthenia Gravis.*

Figure 8. ***Participants with sustained CR demonstrated significantly greater improvements in Neuro-QoL Fatigue versus those with transient CR and no CR***



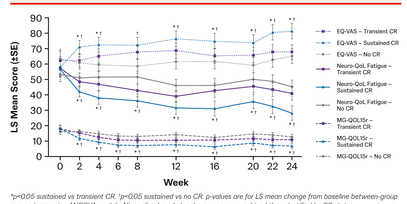
CR is an improvement of ≥2 points in MG-ADL total score and ≥3 points in QMG score. Nipocalimab and placebo groups are combined then stratified by CR status.
***CI**=confidence interval, **CR**=composite response, **LS**=least squares, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **Neuro-QoL Fatigue**=Quality of Life in Neurological Disorders Fatigue, **QMG**=Quantitative Myasthenia Gravis.*

Figure 9. ***Participants with sustained CR demonstrated significantly greater improvements in EQ-VAS versus those with transient CR and no CR***



CR is an improvement of ≥2 points in MG-ADL total score and ≥3 points in QMG score. Nipocalimab and placebo groups are combined then stratified by CR.
***CI**=confidence interval, **CR**=composite response, **EQ-VAS**=EuroQol-5-Dimension-5-Level visual analog scale, **LS**=least squares, **MG-ADL**=Myasthenia Gravis Activities of Daily Living, **QMG**=Quantitative Myasthenia Gravis.*

Figure 10. ***Significantly greater improvements in MG-QOL15r, Neuro-QoL Fatigue, and EQ-VAS were demonstrated in participants achieving sustained CR at week 2 and maintained through week 24***



**p<0.05 sustained vs transient CR. †p<0.05 sustained vs no CR. p-values are for LS mean change from baseline between-group comparisons using ANCOVA models. Nipocalimab and placebo groups are combined then stratified by CR status.*
***ANCOVA**=analysis of covariance, **CR**=composite response, **EQ-VAS**=EuroQol-5-Dimension-5-Level visual analog scale, **LS**=least squares, **MG-QOL15r**=Myasthenia Gravis Quality of Life 15-item revised, **Neuro-QoL Fatigue**=Quality of Life in Neurological Disorders Fatigue, **SE**=standard error.*

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