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# Quality of Life in Patients with Generalized Myasthenia Gravis Achieving Sustained vs Transient Minimal Symptom Expression in the Phase 3 Vivacity-MG3 Trial

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## Background

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

In the phase 3 Vivacity-MG3 study (NCT04951622), participants with gMG who received nivalimab demonstrated improved and sustained efficacy versus those receiving placebo<sup>3</sup>

Minimal symptom expression (MSE), defined as a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of  $\leq 1$ , is a treatment goal in gMG;<sup>4</sup> however, functional outcomes associated with achieving sustained MSE have not been fully explored

## Objective

The purpose of this post-hoc analysis was to evaluate MSE treatment response and quality of life in participants achieving sustained versus transient MSE in Vivacity-MG3

## Methods

### Participants

- This Vivacity-MG3 post-hoc analysis included participants in the prespecified efficacy analysis population
  - Randomized participants who received  $\geq 1$  dose of study drug (nivalimab or placebo) in the double-blind phase and were antibody positive for a gMG-related pathogenic antibody (anti-acetylcholine receptor, anti-muscle-specific tyrosine kinase, or anti-lipoprotein-receptor-related protein 4)

- Participants were stratified into groups based on MSE status over 24 weeks in the double-blind phase:
  - Never achieved MSE (no MSE)
  - Achieved MSE at least once but was not sustained for  $\geq 8$  weeks (transient MSE)
  - Achieved MSE and was sustained for  $\geq 8$  weeks (sustained MSE)

### Assessments

- The proportion of participants achieving and sustaining MSE was evaluated for nivalimab versus placebo
- Logistic regression models compared likelihood (odds ratio) of achieving transient or sustained MSE (reference = no MSE) for nivalimab versus placebo
- Treatment groups were combined, stratified by MSE status, and then the impact of MSE status on quality of life was evaluated
  - Least squares mean change from baseline in Myasthenia Gravis Quality of Life-15 revised (MG-QoL-15r) total score was compared across MSE groups using analysis of covariance (ANCOVA) models at Week 24 with fixed effects for group, autoantibody status, and region, and baseline score as covariates

## Key Takeaways

- In this Vivacity-MG3 post-hoc analysis, nivalimab-treated participants with gMG were four times more likely to achieve and sustain MSE for  $\geq 8$  weeks compared with those receiving placebo
- Participants achieving sustained MSE demonstrated greater improvements in MG-QoL-15r scores than those with transient MSE, reflecting meaningful improvements in patient-reported quality of life
- These findings suggest  $\geq 8$ -week sustained MSE delivers clinically relevant quality of life benefits and should be considered as an important patient-centered treatment goal for patients with gMG receiving advanced treatments

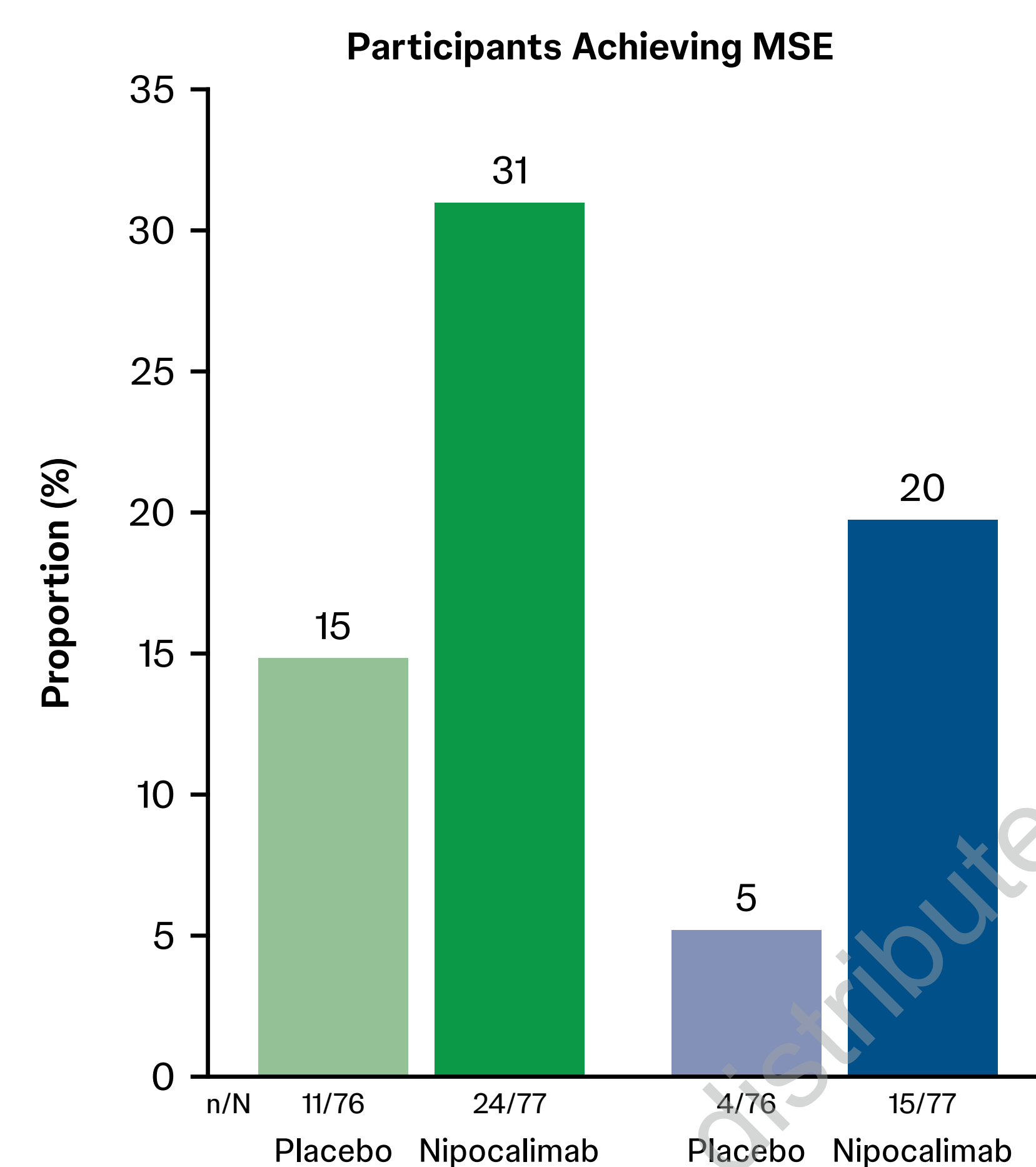
## Results

### Baseline participant characteristics

	Nivalimab + SOC (n=77)	Placebo + SOC (n=76)	Total (n=153)
Age, years, mean (SD)	52.5 (15.66)	52.3 (16.37)	52.4 (15.97)
Sex, female, n (%)	50 (64.9)	42 (55.3)	92 (60.1)
Baseline MG-ADL total score, mean (SD)	9.4 (2.73)	9.0 (1.97)	9.2 (2.38)
Baseline MG-QoL-15r total score, mean (range)	15.5 (5.0–28.0)	16.9 (0.0–28.0)	16.2 (0.0–28.0)
Baseline QMG total score, mean (SD)	15.1 (4.78)	15.7 (4.92)	15.4 (4.85)
Antibody positive at screening, n (%)			
AChR	63 (81.8)	71 (93.4)	134 (87.6)
MuSK	12 (15.6)	4 (5.3)	16 (10.5)
LRP4	2 (2.6)	1 (1.3)	3 (2.0)

AChR=acetylcholine receptor, LRP4=lipoprotein-receptor-related protein 4, MG-ADL=Myasthenia Gravis Activities of Daily Living, MG-QoL-15r=Myasthenia Gravis Quality of Life-15 revised, MuSK=muscle-specific tyrosine kinase, QMG=Quantitative Myasthenia Gravis, SD=standard deviation, SOC=standard of care.

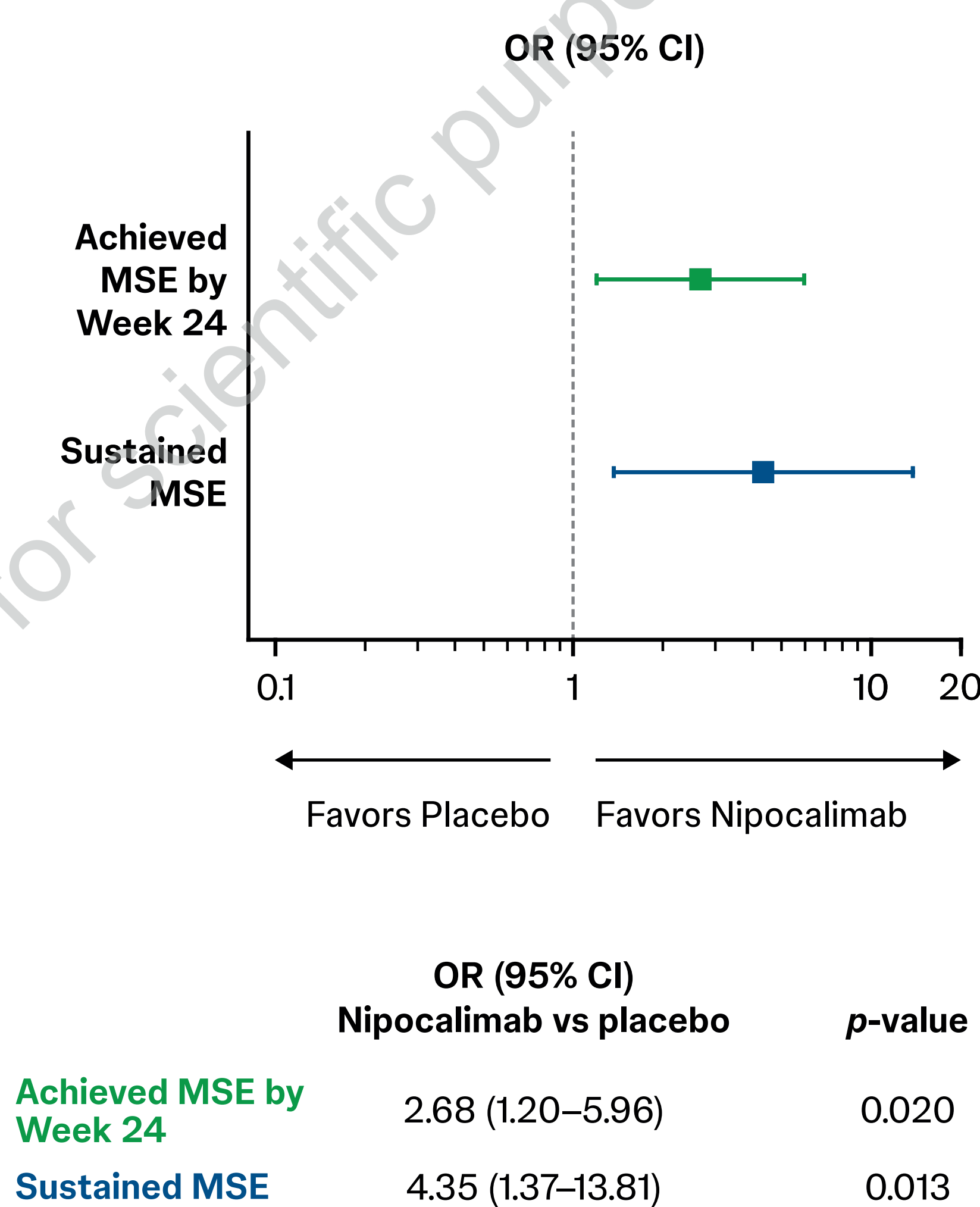
### Proportion of participants in each treatment group who achieved MSE by Week 24 and $\geq 8$ -week sustained MSE



MSE=minimal symptom expression.

- Of 153 participants included in this analysis, 35 (23%) achieved MSE by Week 24 and 19 (12%) had sustained MSE

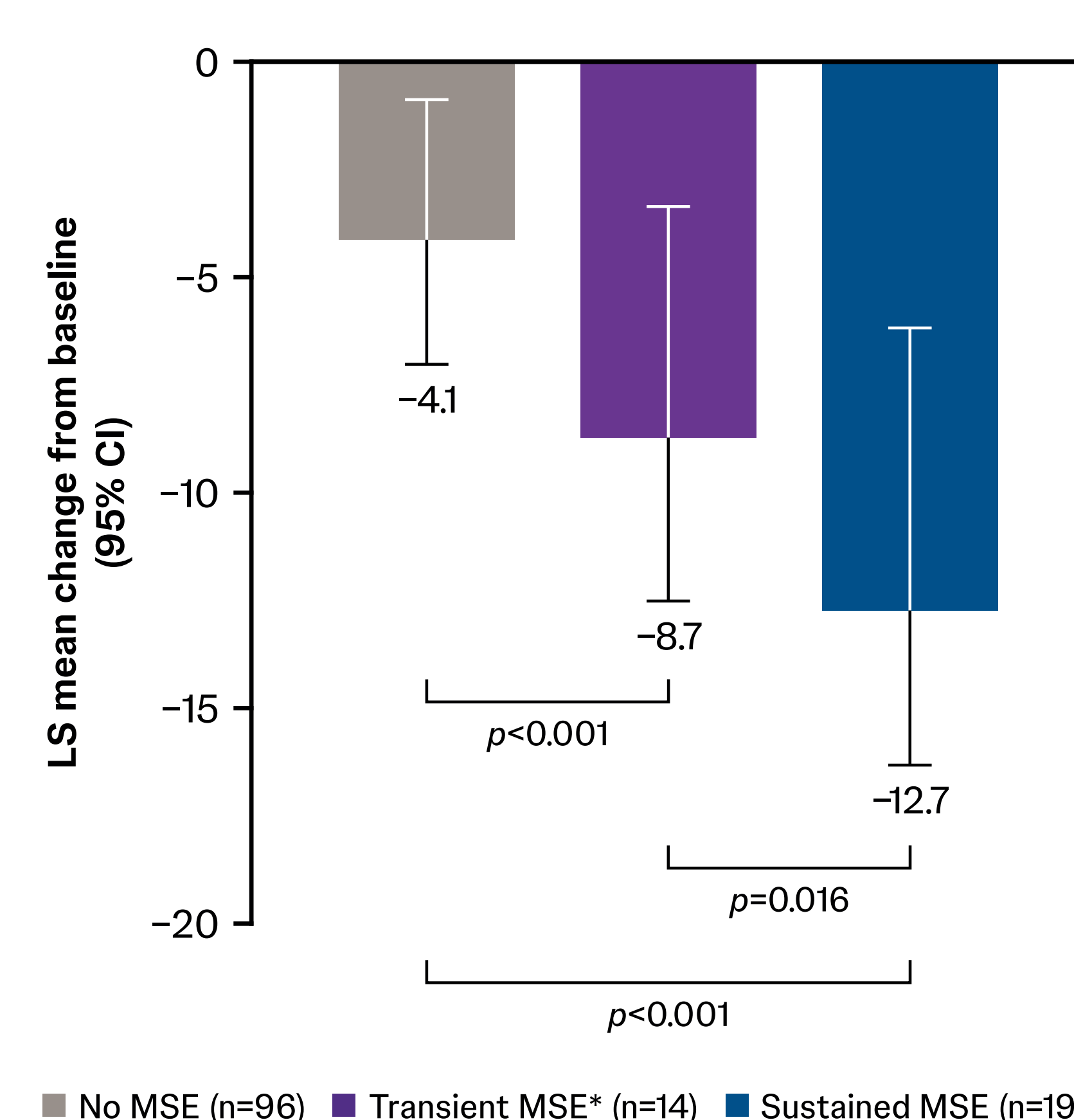
### Treatment effect for achieving MSE by Week 24 and $\geq 8$ -week sustained MSE. Nivalimab-treated participants were significantly more likely to achieve and sustain MSE versus placebo-treated participants



p-values are from Fisher's exact test.

CI=confidence interval, MSE=minimal symptom expression, OR=odds ratio.

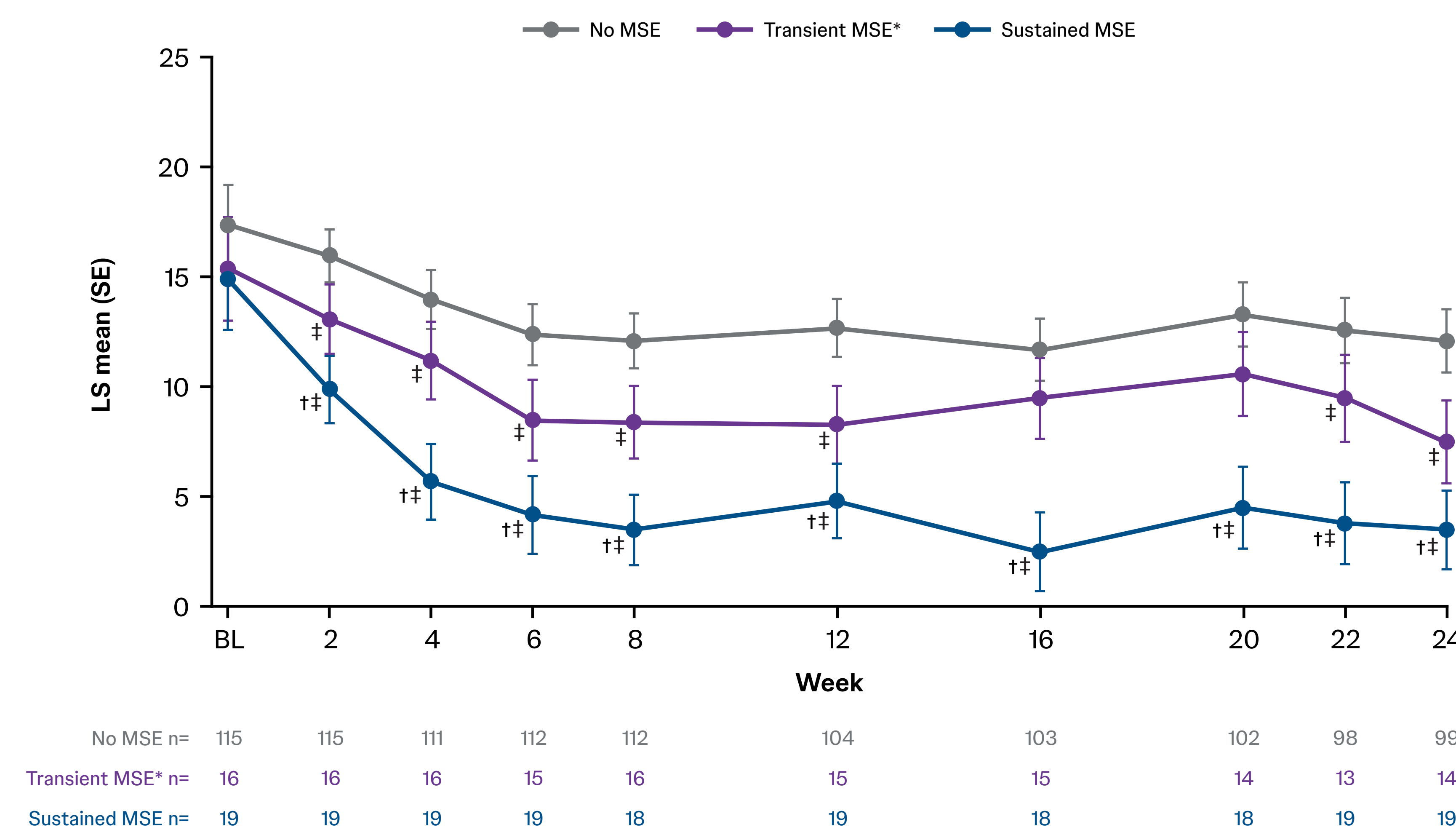
### MG-QoL-15r improvement at Week 24. Participants who achieved sustained MSE demonstrated significantly greater improvements in MG-QoL-15r scores versus those with transient MSE and versus those with no MSE



p-values are for change from baseline between group comparisons from an ANCOVA model with fixed effects for group, autoantibody status, and region, and baseline score as covariates. \*The transient MSE cohort only includes patients who did not meet the sustained MSE condition during the 24-week follow-up period.

ANCOVA=analysis of covariance, CI=confidence interval, LS=least squares, MG-QoL-15r=Myasthenia Gravis Quality of Life-15 revised, MSE=minimal symptom expression.

### MG-QoL-15r improvement over time. Significantly greater improvements in MG-QoL-15r scores were demonstrated in participants achieving sustained MSE at Week 2 and maintained through Week 24 compared with those achieving transient MSE and those not achieving MSE



p-values are for change from baseline between group comparisons from an ANCOVA model with fixed effects for group, autoantibody status, and region, and baseline score as covariates. \*The transient MSE cohort only includes patients who did not meet the sustained MSE condition during the 24-week follow-up period. †p<0.05 vs transient MSE. ‡p<0.05 vs no MSE.

ANCOVA=analysis of covariance, BL=baseline, LS=least squares, MG-QoL-15r=Myasthenia Gravis Quality of Life-15 revised, MSE=minimal symptom expression, SE=standard error.