

Corticosteroid Usage in Patients With Generalized Myasthenia Gravis Receiving Nipocalimab: Phase 3 Vivacity-MG3 Open-Label Extension

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Introduction

- Nipocalimab is a fully human monoclonal antibody that binds the neonatal Fc receptor (FcRn) with high specificity and affinity, reducing circulating immunoglobulin G (IgG), including pathogenic IgG autoantibodies^{1,2}
- Nipocalimab is approved for the treatment of generalized myasthenia gravis (gMG) in adult and adolescent patients who are anti-acetylcholine receptor (AChR) and anti-muscle-specific tyrosine kinase (MuSK) antibody-positive^{3,4}
- In the phase 3 Vivacity-MG3 study, nipocalimab demonstrated sustained disease control, with improvements in MG-Activities of Daily Living (MG-ADL) and Quantitative MG (QMG) total scores versus placebo during the 24-week double-blind phase and through Week 96 of the open-label extension (OLE) phase^{5,6}
 - Corticosteroid dose adjustment was prohibited during the double-blind phase but permitted in the OLE, where all patients received nipocalimab

Objective

To characterize corticosteroid usage, patterns of corticosteroid dose reduction/discontinuation, and symptom improvements among patients with gMG treated with nipocalimab during the OLE phase of the Vivacity-MG3 study

Methods

- Vivacity-MG3 (NCT04951622) is a double-blind, randomized, placebo-controlled, multicenter, phase 3 study evaluating efficacy and safety of nipocalimab in adults with gMG¹
 - Tapering of concomitant gMG medications was allowed only in the OLE phase at every 4 weeks, if the disease has been stable in the past 4 weeks as reflected by MG-ADL scores and based on the investigator's discretion
- Analyses were conducted in patients who were seropositive (anti-AChR, anti-MuSK, or anti-low-density lipoprotein-related protein receptor 4 [LRP4])
- Corticosteroid doses (mg/day prednisone equivalent [eq]) were evaluated during the OLE phase through data cutoff (August 2024)
- The following assessments were evaluated among patients who received corticosteroids at OLE baseline:
 - Mean steroid dose reduction
 - % of patients reaching ≤10 mg/day or ≤5 mg/day prednisone eq, or discontinuing corticosteroid
 - Safety
- The following assessments were evaluated among patients who reached a low corticosteroid dose (≤10 mg/day or ≤5 mg/day) at data cutoff:
 - % of patients who achieved minimal clinical improvement (MCI) of ≥2 points from baseline in MG-ADL total score
 - % of patients who achieved sustained MCI (≥8 weeks)
 - % of patients who achieved minimum symptom expression (MSE; MG-ADL score = 0/1)
 - % of patients who achieved sustained MSE (≥8 weeks; ≥12 weeks)

Results

Patient demographics and baseline characteristics of patients receiving corticosteroids at OLE

- A total of 89 patients received corticosteroids at OLE baseline (44 patients in the Placebo/Nipocalimab group and 45 patients in the Nipocalimab/Nipocalimab group)
- The average duration of follow-up was 68.1 weeks (All Nipocalimab)

Table 1. Demographics and baseline characteristics in patients receiving corticosteroids*

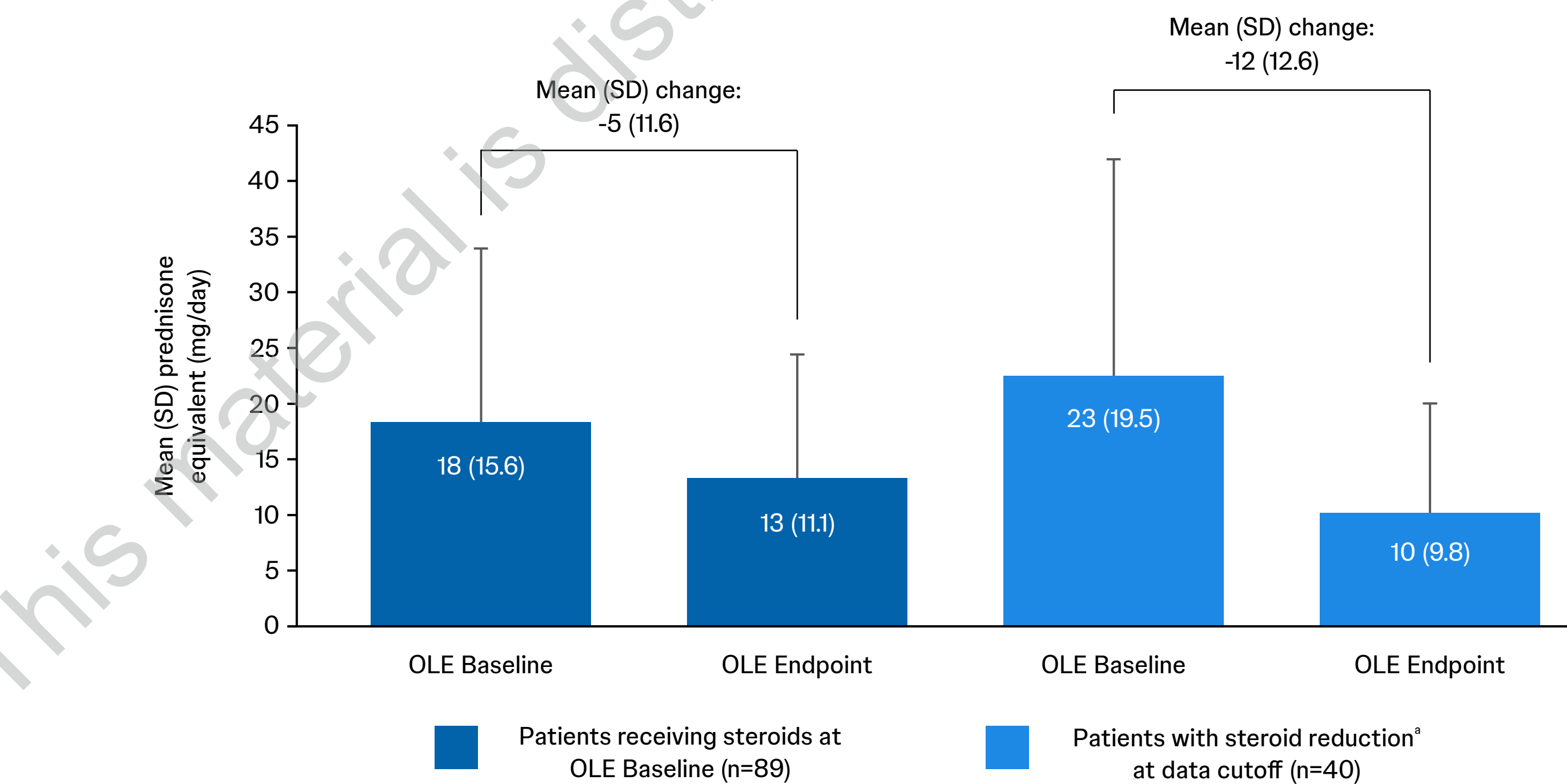
	Placebo/Nipocalimab (n=44)	Nipocalimab/Nipocalimab (n=45)	All Nipocalimab (n=89)
Age, mean (SD), years	51.9 (16.89)	49.7 (15.15)	50.8 (15.98)
Sex, female, n (%)	27 (61.4)	27 (60.0)	54 (60.7)
BMI, mean (SD), kg/m ²	28.3 (5.89)	27.7 (5.58)	28.0 (5.71)
Baseline MG-ADL total score, mean (SD)	9.1 (2.00)	9.4 (2.92)	9.2 (2.50)
Baseline QMG total score, mean (SD)	16.4 (4.94)	15.4 (5.06)	15.9 (5.00)
Antibody positive at screening, n (%)			
Anti-AChR+	39 (88.6)	35 (77.8)	74 (83.1)
Anti-MuSK+	4 (9.1)	9 (20.0)	13 (14.6)
Anti-LRP4+	1 (2.3)	1 (2.2)	2 (2.2)

*Baseline for double-blind period. AChR=acetylcholine receptor, BMI=body mass index, LRP4=low-density lipoprotein receptor-related protein 4, MG-ADL=Myasthenia Gravis-Activities of Daily Living, MuSK=muscle-specific kinase, OLE=open-label extension, QMG=quantitative myasthenia gravis, SD=standard deviation.

Corticosteroid use during OLE

- Of 89 patients receiving corticosteroids at OLE baseline, 40 (45%) reduced or discontinued corticosteroids by data cutoff
 - Among these patients, the mean (SD) steroid dose reduced from 23 to 10 mg/day prednisone eq (Figure 2)
- A total of three patients (3/89; 3%) had a steroid dose increase (greater dose at data cutoff versus baseline)

Figure 2. Mean corticosteroid dose at OLE baseline and OLE endpoint (data cutoff) among patients receiving corticosteroids at OLE baseline and those with steroid reduction at data cutoff



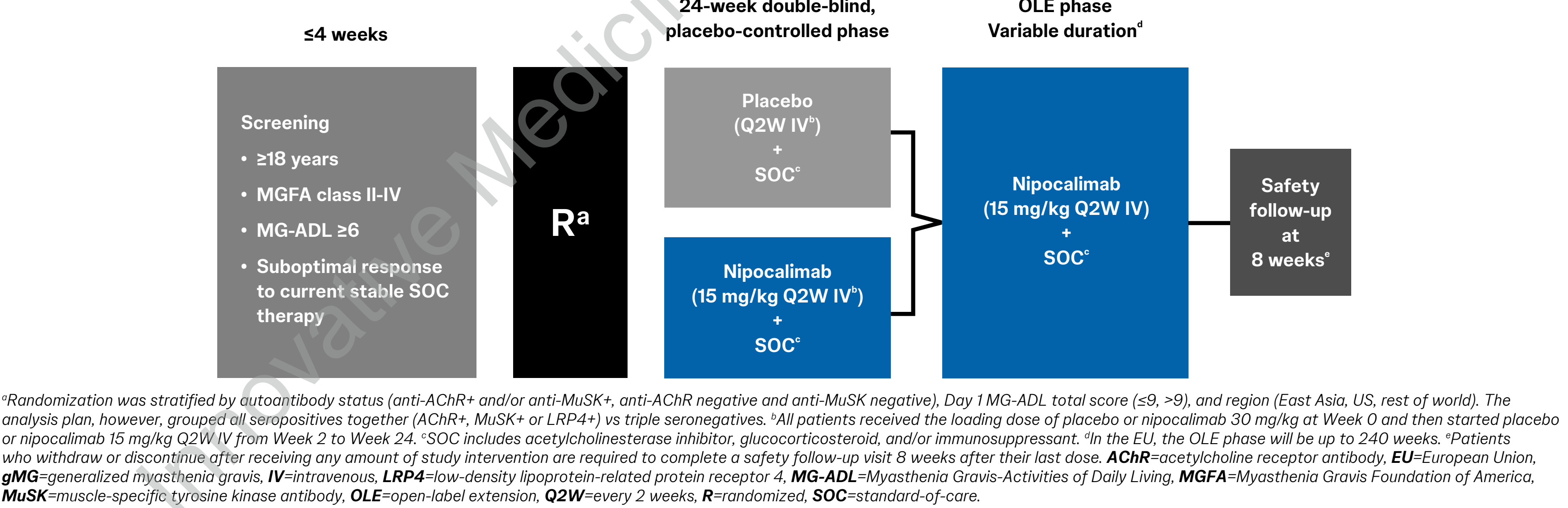
The data cutoff date: August 24, 2024. *Reduction defined as a decreased dose or discontinuation of steroid. OLE=open-label extension, SD=standard deviation.



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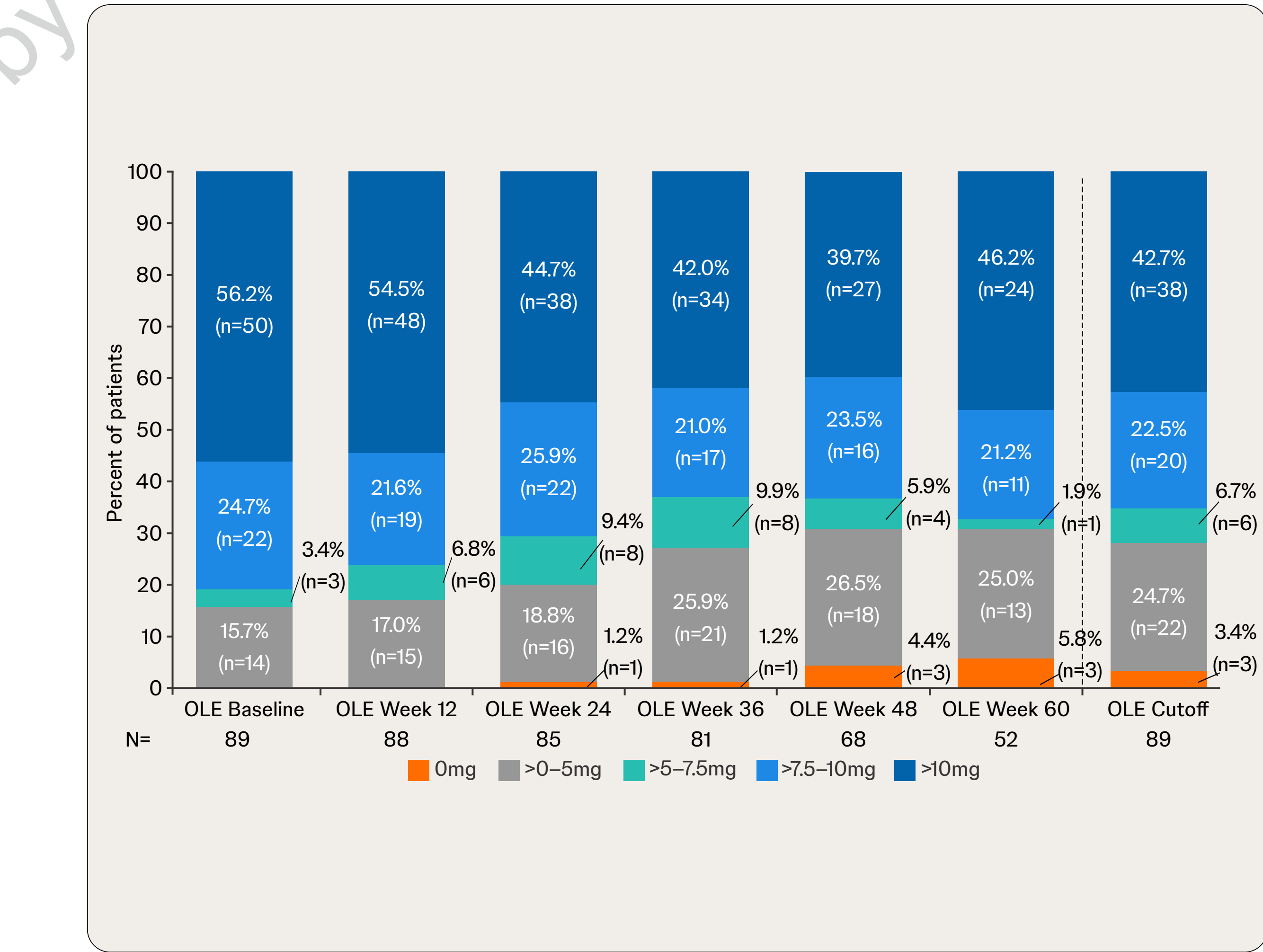
Figure 1. Study design*



Achievement of MCI and MSE among patients reaching a low corticosteroid dose

- Corticosteroid use decreased over time during the OLE phase (Figure 3)
- At data cutoff, 57.3% of patients reached ≤10 mg prednisone eq per day
- Sustained disease control was observed in patients who reached ≤10 mg/day or ≤5 mg/day prednisone eq doses at OLE data cutoff (Figure 4)
- Among patients who had MSE at any time, median (IQR) duration of MSE was:
 - 12.1 (0–46 weeks) for those on ≤10 mg/day prednisone eq at OLE cutoff (n=22)
 - 43.9 (4–58.9 weeks) for those on ≤5 mg/day prednisone eq at OLE cutoff (n=13)

Figure 3. Proportion of patients in each corticosteroid dose group over time



The data cutoff date: August 24, 2024. MCI=minimal clinical improvement, MSE=minimum symptom expression, OLE=open-label extension.

Safety

- The safety profile of nipocalimab in patients receiving corticosteroids was consistent with that in the overall population (Table 2)

Table 2. Summary of TEAEs during the OLE: patients receiving corticosteroids at OLE baseline

	Placebo/Nipocalimab (n=44)	Nipocalimab/Nipocalimab (n=45)	All Nipocalimab (n=89)
Average duration of follow-up, weeks	68.46	67.75	68.10
All AEs, n (%)	42 (95.5)	38 (84.4)	80 (89.9)
Treatment-related	20 (45.5)	15 (33.3)	35 (39.3)
Serious AEs, n (%)	9 (20.5)	12 (26.7)	21 (23.6)
Treatment-related*	4 (9.1)	1 (2.2)	5 (5.6)
AEs leading to treatment discontinuation, n (%)	6 (13.6)	3 (6.7)	9 (10.1)
Infections and Infestations, n (%)	32 (72.7)	23 (51.1)	55 (61.8)
Infusion-related reactions, n (%)	0	0	0
Adjudicated MACE, n (%)			
Fatal	1 (2.3) ^b	1 (2.2) ^c	2 (2.2)
Non-fatal	1 (2.3)	0	1 (1.1)

The data cutoff date: August 24, 2024. *Included cellulitis (n=1), pneumonia (n=1), hemophagocytic lymphohistiocytosis (n=1), and weight increased (n=1) in the Placebo/Nipocalimab group, and Epstein-Barr virus infection (n=1) in the Nipocalimab/Nipocalimab group. ^bMyocardial infarction, deemed unrelated to the study drug. ^cUnrelated to the study drug. AE=adverse event, MACE=major adverse cardiovascular event, OLE=open-label extension, TEAE=treatment-emergent adverse event.

Key Takeaways

- During the Vivacity-MG3 OLE phase, nearly half of patients receiving corticosteroids at baseline reduced or discontinued corticosteroids
- A substantial portion of patients who reached a low dose corticosteroid (≤10 or ≤5 mg/day prednisone eq) during the OLE achieved sustained MCI or MSE (≥8 weeks)
- These results support the corticosteroid-sparing effect of nipocalimab and concurrent meaningful clinical improvement and sustained disease control in patients with gMG