

Corticosteroid Use in Nipocalimab-Treated Japanese Patients with Generalized Myasthenia Gravis: Phase 3 Vivacity-MG3 Open-Label Extension Study

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Introduction

- Generalized myasthenia gravis (gMG), a rare chronic condition, is characterized by pathogenic immunoglobulin G (IgG) autoantibody-mediated impairment of neurotransmission leading to fatigable muscle weakness^{1,2}
- Nipocalimab is a fully human monoclonal antibody that binds the neonatal Fc receptor (FcRn) with high affinity and specificity, reducing circulating levels of IgG, including pathogenic IgG-based autoantibodies^{3,4}
- In seropositive adults with gMG, nipocalimab plus standard-of-care (SOC) treatment demonstrated sustained disease control versus placebo plus SOC during the 24-week double-blind phase of the VIVACITY-MG3 study^{5,6}
 - Sustained disease control was maintained through open-label extension (OLE) week 60⁷
 - During the OLE, 45% of patients receiving nipocalimab reduced or discontinued corticosteroids; a substantial proportion demonstrated minimum symptom expression (MSE; MG-Activities of Daily Living [MG-ADL] score=0/1) and sustained for ≥8 weeks⁷
- In Japan, achieving minimal symptoms with low corticosteroid doses (≤5 mg/day) is an important treatment goal in gMG

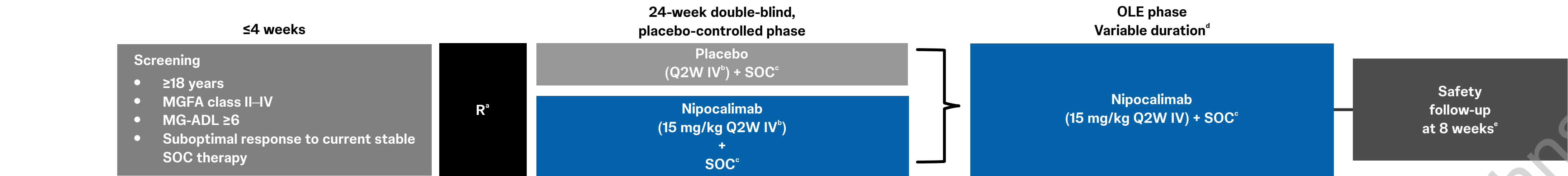
Objective

To characterize the impact of nipocalimab on corticosteroid use in patients, specifically in Japanese patients, 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 gMG⁵
 - 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

Figure 1. Study Design⁵



*Randomization was stratified by autoantibody status (anti-AChR+ and/or anti-MuSK+, anti-AChR negative and anti-MuSK negative), Day 1 MG-ADL total score (≤9, >9), and region (East Asia, US, rest of world). The analysis plan, however, grouped all seropositives together (AChR+, MuSK+ or LRP4+) vs triple seronegatives. *All patients received the loading dose of placebo or nipocalimab 30 mg/kg at Week 0 and then started placebo or nipocalimab 15 mg/kg Q2W IV from Week 2 to Week 24. *SOC includes acetylcholinesterase inhibitor, glucocorticosteroid, and/or immunosuppressant. *In the EU, the OLE phase will be up to 240 weeks. *Participants who withdraw or discontinue after receiving any amount of study intervention are required to complete a safety follow-up visit 8 weeks after their last dose.

AChR=acetylcholine receptor, EU=European Union, gMG=generalized myasthenia gravis, IV=intravenous, LRP4= low-density lipoprotein receptor-related protein 4, MG-ADL=Myasthenia Gravis-Activities of Daily Living, MGFA=Myasthenia Gravis Foundation of America, MuSK=muscle-specific tyrosine kinase, OLE=open-label extension, Q2W=every 2 weeks, R=randomized, SOC=standard-of-care.

Results

Patient demographics and baseline characteristics of Japanese patients receiving corticosteroids

- A total of 11 seropositive Japanese patients received corticosteroids at OLE

Table 1. Patient demographics and baseline characteristics of Japanese patients receiving corticosteroids^a

	Placebo/ Nipocalimab (n=8)	Nipocalimab/ Nipocalimab (n=3)	All Nipocalimab (n=11)
Age, mean (SD), years	59.1 (13.30)	54.3 (11.85)	57.8 (12.53)
Sex, female, n (%)	7 (87.5)	3 (100.0)	10 (90.9)
BMI, mean (SD), kg/m ²	28.0 (6.80)	31.2 (2.10)	28.9 (5.96)
Baseline MG-ADL total score, mean (SD)	9.1 (1.81)	10.7 (1.53)	9.5 (1.81)
Baseline QMG total score, mean (SD)	16.0 (4.09)	14.3 (1.76)	15.5 (3.59)
Antibody positive at screening, n (%)			
Anti-AChR+	7 (87.5)	2 (66.7)	9 (81.8)
Anti-MuSK+	0	1 (33.3)	1 (9.1)
Anti-LRP4+	1 (12.5)	0	1 (9.1)

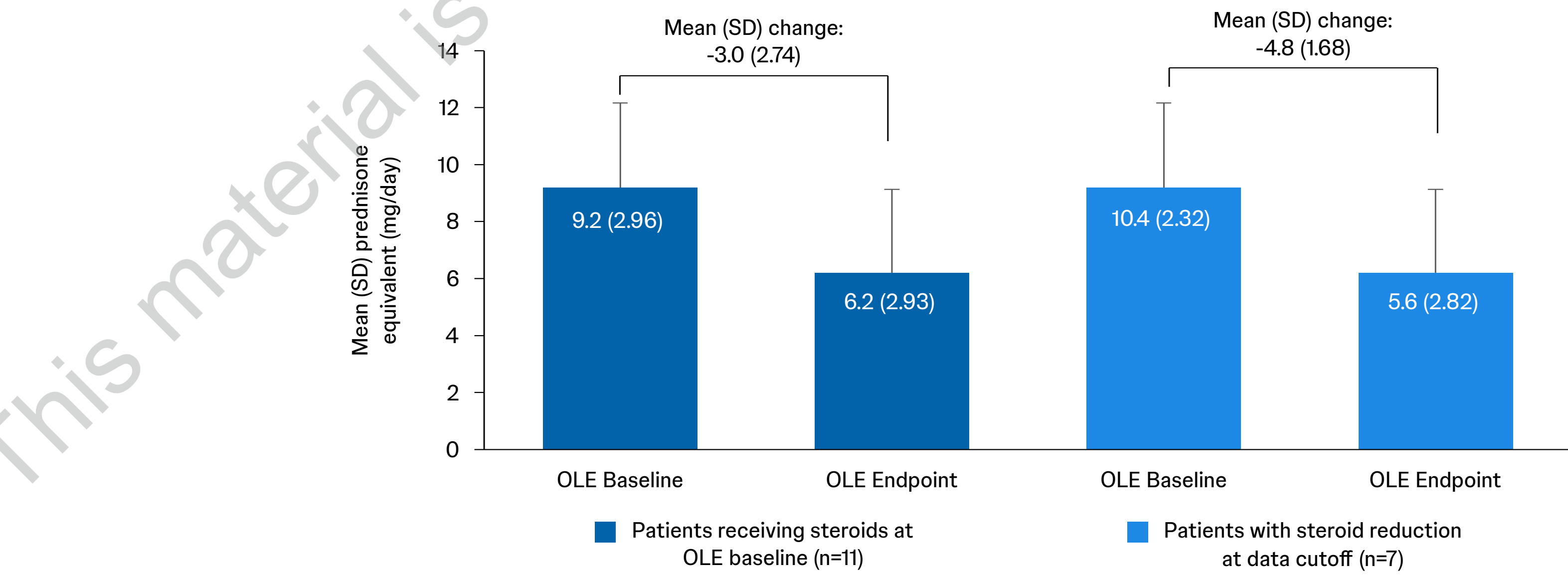
^aBaseline for double-blind period.

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 in Japanese patients during OLE

- Among 11 patients receiving corticosteroids at OLE baseline, 7 (64%) reduced corticosteroids by data cutoff
- Overall, mean (SD) steroid dose reduced from 9.2 (2.96) to 6.2 (2.93) mg/day prednisone equivalent (Figure 2)
- Among those reducing steroid (n=7):
 - Mean (SD) dose reduced from 10.4 (2.32) to 5.6 (2.82) mg/day prednisone equivalent
 - 5/7 (71%) reached ≤5 mg/day

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



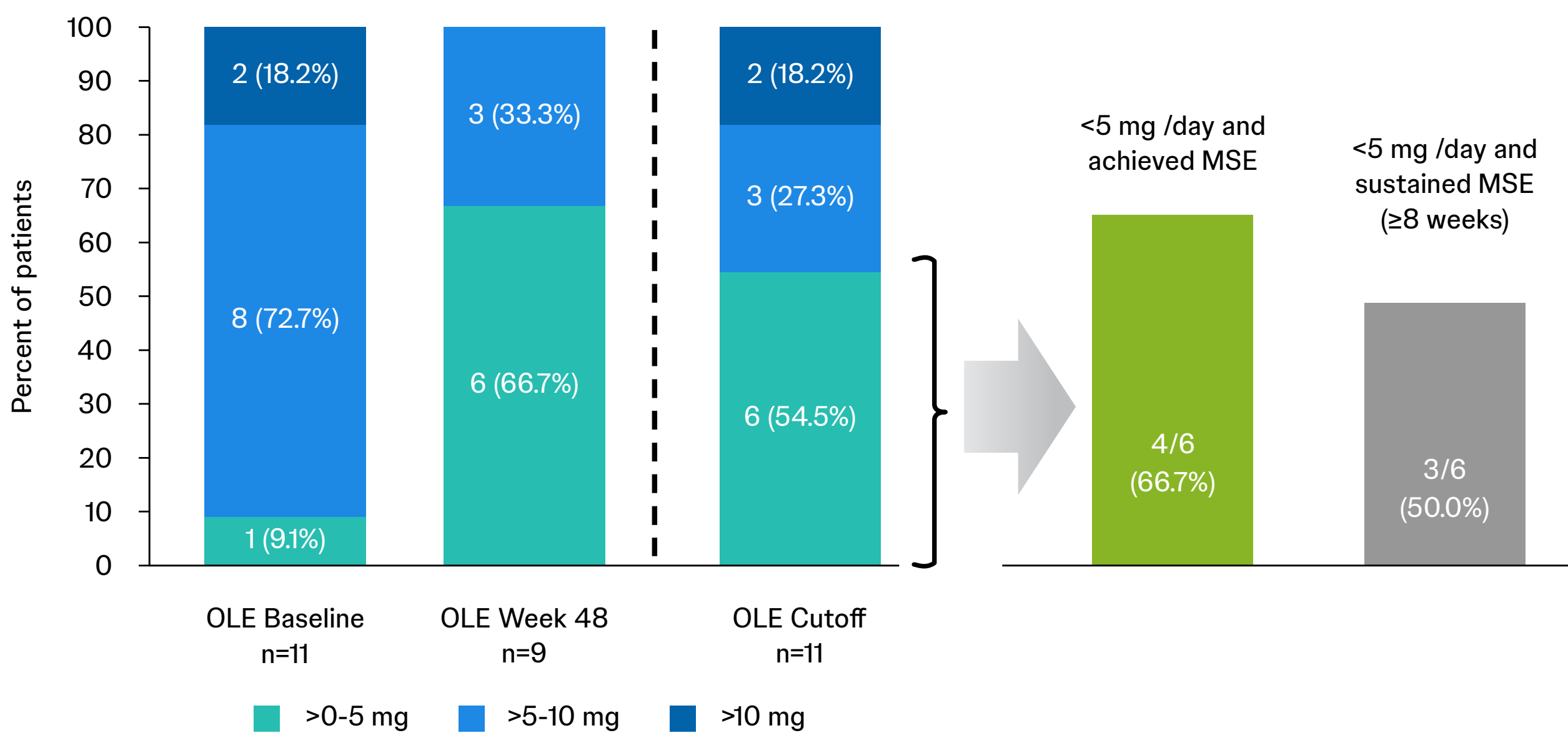
Data cutoff date: August 24, 2024.

OLE=open-label extension, SD=standard deviation.

Distribution of corticosteroid dose groups at OLE baseline, OLE Week 48, and data cutoff

- Among the 6 patients on ≤5 mg/day prednisone equivalent at data cutoff:
 - 4 (66.7%) achieved MSE by data cutoff
 - 3 (50.0%) achieved sustained MSE (≥8 weeks) by data cutoff

Figure 3. Distribution of corticosteroid dose groups at OLE baseline, OLE Week 48, and at data cutoff



Data cutoff date: August 24, 2024 (median follow-up: 76 weeks). Prednisone (mg) at each week equals the mean daily prednisone dose for the 28 days prior to and including that week.

MSE=minimum symptom expression, OLE=open-label extension.

Safety

- No new safety signals were observed in Japanese patients receiving corticosteroids (Table 2)

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

	Placebo/ Nipocalimab (n=8)	Nipocalimab/ Nipocalimab (n=3)	All Nipocalimab (n=11)
Average duration of follow-up, weeks	59.36	96.81	69.57
All AEs, n (%)	8 (100.0)	3 (100.0)	11 (100.0)
Treatment-related	4 (50.0)	1 (33.3)	5 (45.5)
Serious AEs, n (%) ^a	2 (25.0)	1 (33.3)	3 (27.3)
Treatment-related	2 (25.0)	0	2 (18.2)
AEs leading to treatment discontinuation, n (%)	2 (25.0)	0	2 (18.2)
Infections and Infestations, n (%)	7 (87.5)	1 (33.3)	8 (72.7)
Infusion-related reactions, n (%)	0	0	0
Adjudicated MACE, n (%)	0	0	0

^aSerious AEs included hemophagocytic lymphohistiocytosis (n=1) and cellulitis (n=1) in the Placebo/Nipocalimab group, and back pain (n=1) and myasthenia gravis (n=1) in the Nipocalimab/Nipocalimab group

Data cutoff date: August 24, 2024.

AE=adverse event, MACE=major adverse cardiovascular event, OLE=open-label extension, TEAE=treatment-emergent adverse event.