

Effect of Nipocalimab on Sustained Disease Control During Infections: Post-Hoc Analysis of the VIVACITY-MG3 Study in Myasthenia Gravis

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Introduction

- Generalized myasthenia gravis (gMG) is an autoantibody-driven disorder characterized by disruption of neurotransmission that severely affects daily functioning and quality of life in patients^{1,2}
- Nipocalimab is the first and the only neonatal Fc receptor (FcRn) blocker approved for the treatment of gMG in anti-acetylcholine receptor (AChR) or anti-muscle-specific kinase (MuSK) antibody-positive adult and adolescent (≥12 years of age) patients^{3,4}
- In the phase 3 Vivacity-MG3 study, nipocalimab+standard-of-care (SOC) treatment demonstrated substantial reduction of immunoglobulin G (IgG) levels, including pathogenic IgG, when compared to placebo+SOC. Nipocalimab also demonstrated sustained improvements in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) total scores during the 24-week study⁵
 - Patients treated with nipocalimab+SOC experienced adverse events of infections and infestations, with incidences that were comparable with placebo+SOC arm, 42/98 (43%), in each arm⁵
- Infections can contribute to symptom exacerbations in gMG; therefore, monitoring MG-ADL and QMG total scores would help assess the symptom control and therapeutic adequacy during episodes of infections⁶

Objective

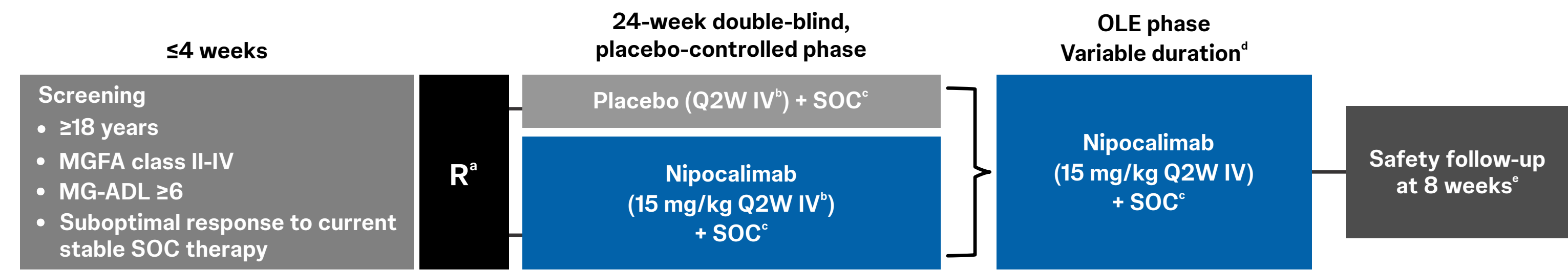
To evaluate the efficacy of nipocalimab treatment during/shortly after infection episodes in the double-blind phase of Vivacity-MG3 by measuring changes in MG-ADL and QMG scores

Methods

Study Design

- Vivacity-MG3 was a multicenter, randomized, double-blind, placebo-controlled study evaluating efficacy, safety, pharmacokinetics, and pharmacodynamics of nipocalimab in adults with gMG⁵

Figure 1. Study design⁵



*Randomization was stratified by autoantibody status (anti-AChR positive or anti-MuSK positive or anti-AChR negative and anti-MuSK negative), Day 1 MG-ADL total score (≤5, >5), and region (East Asia, US, and rest of world). The analysis plan, however, grouped all seropositive together (AChR+, MuSK+ or LRP4+) vs triple seronegative. *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 antibody, EU=European Union, IV=intravenous, LRP4=low-density lipoprotein-related protein receptor 4, MG-ADL=Myasthenia Gravis-Activities of Daily Living, MGFA=Myasthenia Gravis Foundation of America, MuSK=muscle-specific tyrosine kinase antibody, OLE=open-label extension, Q2W=every 2 weeks, R=randomized, SOC=standard-of-care, US=United States.

Post-Hoc Analysis

Analysis Sets

- Patients with infections/infestations/serious infections at any timepoint in the double-blind phase were analyzed
- All analyses were completed on the safety analysis set and the primary efficacy analysis sets
- Safety analysis set: Included both seropositive and seronegative patients randomized to receive ≥1 dose (partial or complete) of any study intervention in the double-blind phase
- Primary efficacy set: Included all patients who received ≥1 dose (partial or complete) of study drug in the double-blind phase and were antibody-positive (anti-AChR, anti-MuSK, or anti-low-density lipoprotein-related protein receptor 4 [LRP4]), confirmed before randomization

Assessments

- Pre-infection and post-infection MG-ADL and QMG scores were compared
- Pre-infection MG-ADL/QMG score was the most recent observation recorded within 16 days^a immediately preceding infection start date
- Post-infection MG-ADL/QMG score was the most observation recorded from the infection start date through 16 days^a after the infection end date

^aTime frame where we expected to find at least one MG-ADL/QMG assessment corresponding to an infection event.

Results

Baseline demographics

- The safety analysis set included 196 patients: n=98, nipocalimab+SOC; n=98, placebo+SOC (Table 1)
- The primary efficacy analysis set included 153 antibody-positive patients: n=77, nipocalimab+SOC; n=76, placebo+SOC (Table 1)

Table 1. Patient demographics and baseline characteristics⁵

	Nipocalimab+SOC	Placebo+SOC
Safety analysis set (n=98)		
Age, mean (SD), years	52.9 (15.49)	52.7 (15.60)
Female, n (%)	66 (67.30)	56 (57.10)
Duration of myasthenia gravis, mean (SD), years	6.8 (7.03)	8.9 (8.03)
Baseline MG-ADL total score, mean (SD)	9.5 (2.69)	9.3 (2.01)
Baseline QMG total score, mean (SD)	15.0 (4.80)	15.6 (4.71)
Antibody-positive at screening, n (%)		
Anti-AChR+	63 (64.30)	71 (72.4)
Anti-MuSK+	12 (12.20)	4 (4.10)
Anti-LRP4+	2 (2.00)	1 (1.00)
Primary efficacy analysis set (n=77)		
Age, mean (SD), years	52.5 (15.66)	52.3 (16.37)
Female, n (%)	50 (64.90)	42 (55.30)
Duration of myasthenia gravis, mean (SD), years	6.9 (7.44)	8.9 (8.13)
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)
Antibody-positive at screening, n (%)		
Anti-AChR+	63 (81.80)	71 (93.40)
Anti-MuSK+	12 (15.60)	4 (5.30)
Anti-LRP4+	2 (2.60)	1 (1.30)

Treatment-emergent adverse events—Infections and infestations

- Infection/infestations were reported in 42.9% patients in nipocalimab+SOC group in safety as well as the primary efficacy analysis set (Figure 2)
- COVID-19, nasopharyngitis, and upper respiratory tract infection were the most common events across the groups in both safety as well as primary efficacy analysis sets (Table 2)

Figure 2. Summary of treatment-emergent adverse events of infections and infestations in (A) safety analysis set and (B) primary efficacy analysis set

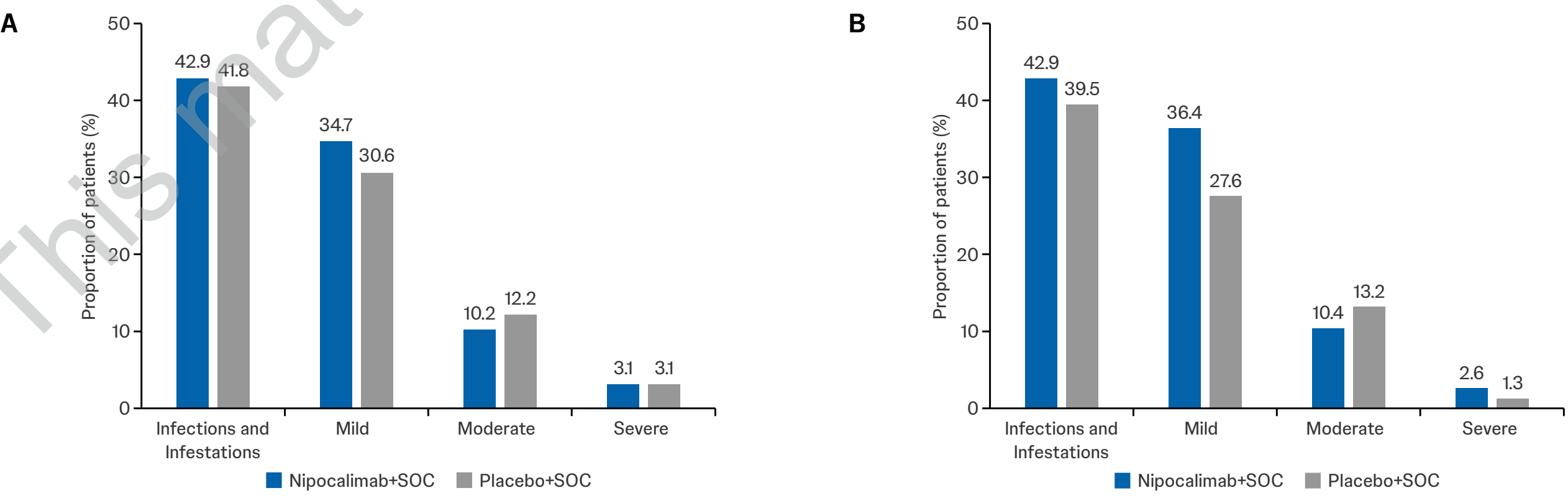


Table 2. Most frequent treatment-emergent adverse events—infections and infestations^a

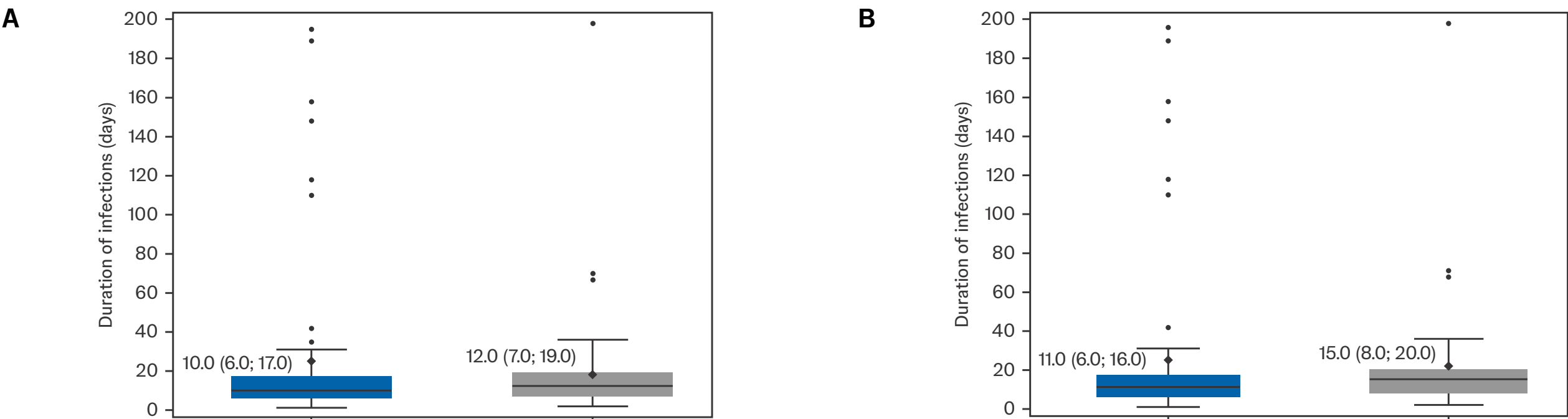
	Nipocalimab+SOC		Placebo+SOC	
	n (%)	Events, n	n (%)	Events, n
Safety Analysis Set				
COVID-19	11 (11.2%)	11	10 (10.2%)	11
Nasopharyngitis	9 (9.2%)	9	10 (10.2%)	11
Upper respiratory tract infection	6 (6.1%)	6	8 (8.2%)	8
Urinary tract infection	5 (5.1%)	5	0	0
Pneumonia	3 (3.1%)	4	1 (1.0%)	1
Primary Efficacy Analysis Set				
COVID-19	9 (11.7%)	9	5 (6.6%)	6
Nasopharyngitis	6 (7.8%)	6	8 (10.5%)	9
Upper respiratory tract infection	4 (5.2%)	4	6 (7.9%)	6
Urinary tract infection	3 (3.9%)	3	0	0
Pneumonia	3 (3.9%)	4	1 (1.3%)	1

^aIncludes all adverse events coded to the system organ class "Infections and infestations." Preferred terms listed are those reported in ≥3% of patients in either treatment group. Events [n] represents the total number of treatment-emergent infection events.

Overall infection duration

- The median (interquartile range, IQR) duration of overall infections was comparable between nipocalimab+SOC and placebo+SOC groups in both safety as well as primary efficacy analysis sets (Figure 3)

Figure 3. Duration of infections^{a,b,c} in (A) safety analysis set and (B) primary efficacy analysis set

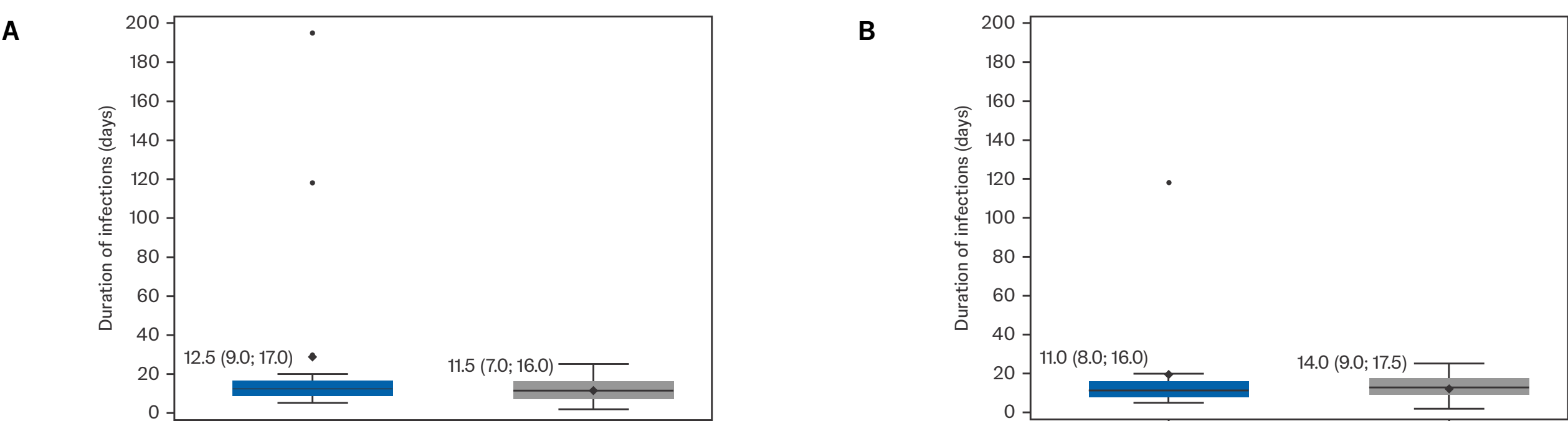


Data are presented as median (IQR) and the bars represent the range. *Duration calculated as infection end date minus infection start date + 1 day. If infection end date is missing, it is imputed with the double-blind phase end date for patient. *A patient could contribute more than one infection if the infections are mutually exclusive in time. *A patient with temporal overlapping infections had the infections combined as one infection using the earliest start date and the latest end date.

Moderate to severe infections duration

- The median (IQR) duration of moderate to severe infections was comparable between nipocalimab+SOC and placebo+SOC groups in both safety as well as primary efficacy analysis sets (Figure 4)

Figure 4. Duration of moderate to severe infections^{a,b,c} in (A) safety analysis set and (B) primary efficacy analysis set

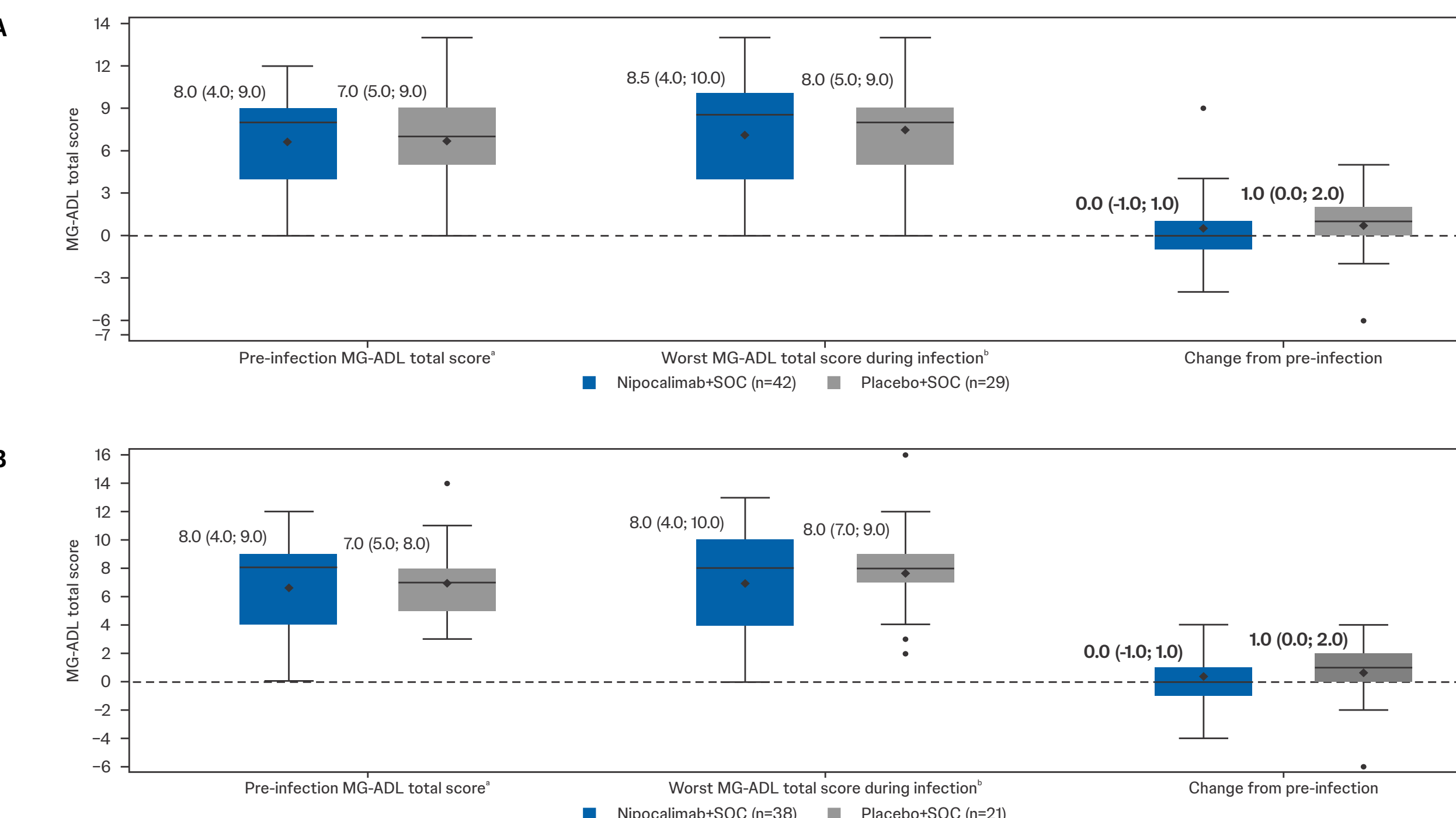


Data are presented as median (IQR) and the bars represent the range. *Duration calculated as infection end date minus infection start date + 1 day. If infection end date is missing, it is imputed with the double-blind phase end date for patient. *A patient could contribute more than one infection if the infections are mutually exclusive in time. *A patient with temporal overlapping infections had the infections combined as one infection using the earliest start date and the latest end date.

MG-ADL score changes during/after infections

- MG-ADL total scores remained generally stable during infections in nipocalimab+SOC treated patients (Figure 5)

Figure 5. MG-ADL scores in (A) safety analysis set and (B) primary efficacy analysis set

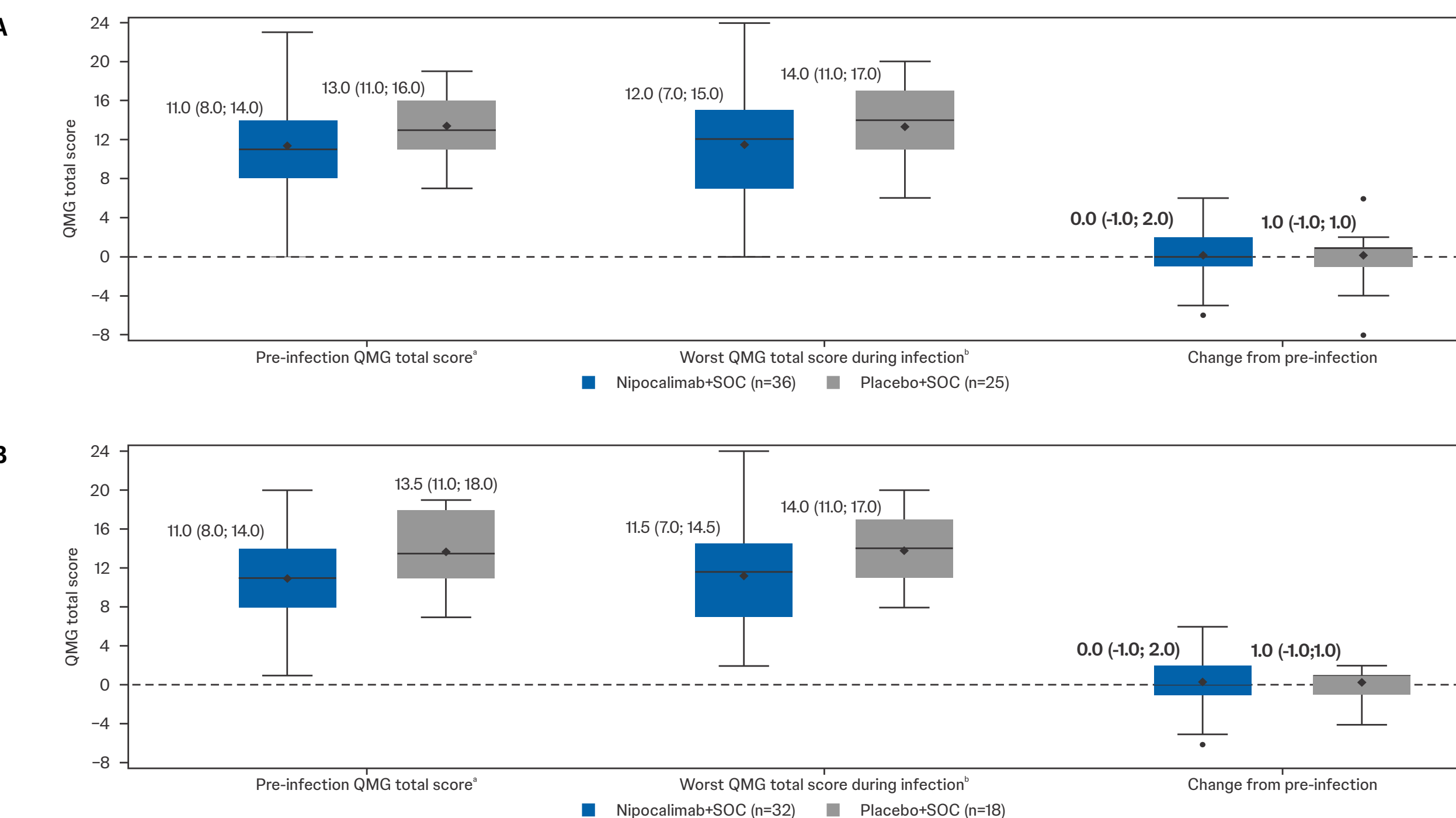


Data are presented as median (IQR) and the bars represent the range. *Latest total score within the 16 days before (and including) the infection start date, and not occurring after an ICE. *Worst total score occurring after the start date and up to (and including) 16 days after the end date, and not occurring after an ICE.

QMG score changes during/after infections

- QMG total scores remained generally stable during infections in nipocalimab+SOC treated patients (Figure 6)

Figure 6. QMG scores in (A) safety analysis set and (B) primary efficacy analysis set



Data are presented as median (IQR) and the bars represent the range. *Latest total score within the 16 days before (and including) the infection start date, and not occurring after an ICE. *Worst total score occurring after the start date and up to (and including) 16 days after the end date, and not occurring after an ICE.