daily doses remained stable in 49.3% and 52.8% of visits despite, respectively, ECLAM=0 and no BILAG activity. Every month spent on PDN<5mg/day was associated with lower damage accrual (IRR 0.96; 95%CI 0.93–0.99; p=0.007) and better GH-VAS (beta 0.60; 95%CI 0.13–1.33; p=0.108), although the latter was statistically nonsignificant.

Conclusion GCs are feasibly tapered to PDN <5mg/day maintenance dose with adequate control of disease activity and lowered damage in patients with newly diagnosed SLE, whereas physicians usually avoid GCs discontinuation in the early disease stage.

PO.6.134 SAFETY AND TOLERABILITY OF NIPOCALIMAB ADMINISTERED AT DIFFERENT RATES OF INTRAVENOUS INFUSION IN HEALTHY ADULTS: A PHASE 1 PLACEBO-CONTROLLED SINGLE-DOSE STUDY

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Purpose Systemic lupus erythematosus (SLE) is an IgG-mediated autoimmune disease. Nipocalimab, which is in clinical development for the treatment of SLE, targets the IgG binding site on neonatal Fc receptor (FcRn) to reduce serum levels of total and pathogenic IgG. The objective of this study was to assess the safety and tolerability of single doses of nipocalimab administered at different IV infusion rates in healthy adults to support the potential use of shortened infusions in future studies.

Methods The trial was a single dose, sequential, randomized, double-blind, placebo-controlled, escalating dose and infusion rate study. Eligible participants were males or females aged 18–55 years with no clinically significant medical or physical conditions. Participants were randomized to 1 of 5 cohorts (n=8 per cohort [6 nipo, 2 placebo]) to receive nipocalimab 30 mg/kg IV infused over 60, 30, 15 or 7.5 min (0.5, 1, 2, or 4 mg/kg/min), nipocalimab 60 mg/kg IV infused over 15 min (4 mg/kg/min) or matching placebo. Safety was assessed by the frequency and nature of treatment-emergent adverse events (TEAEs), as well as abnormalities in laboratory assessments and vital signs.

Results A total of 40 participants received study drug and were included in the safety analysis. A total of 12 participants (40%) experienced TEAEs across all nipocalimab dosing cohorts. The most frequently reported TEAE was headache. None of the TEAEs were severe, and no participants discontinued treatment due to TEAEs; there were no serious adverse events or deaths. Only 4 participants experienced AEs that occurred within 24 hours after the infusion that were considered related to the study drug. Lower rates of nipocalimab infusion were associated with fewer TEAEs, while participants receiving 4 mg/kg/min (as either 30 mg/kg infused over 7.5 min or 60 mg/kg infused over 15 min) reported more TEAEs (Table 1).

Conclusions Single doses of nipocalimab, when administered at doses up to 60 mg/kg and infusion rates up to 4 mg/kg/min were safe and well-tolerated in healthy adults. The frequency of reported TEAEs was lower in participants receiving nipocalimab at rates of 1 or 2 mg/kg/min, providing a target infusion rate for current and future studies.

Abstract PO.6.134 Table 1 TEAEs by dosing cohort (safety population)

	Nipocalimab						
TEAEs, n (%)	30 mg/kg (60 min; 0.5 mg/kg/min)	30 mg/kg (30 min; 1 mg/kg/min)	30 mg/kg (15 min; 2 mg/kg/min)	30 mg/kg (7.5 min; 4 mg/kg/min)	60 mg/kg (15 min; 4 mg/kg/min)	Total	Placebo
Participants dosed	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	30 (100)	10 (100)
Participants with TEAEs	3 (50)	1 (17)	2 (33)	3 (50)	3 (50)	12 (40)	1 (10)
Most frequent TEAEs							
Headache	1 (17)	1 (17)	0	2 (33)	2 (33)	6 (20)	1 (10)
Nausea	0	0	0	1 (17)	2 (33)	3 (10)	0
Vomiting	0	0	0	0	2 (33)	2 (7)	0
Back pain	0	0	1 (17)	0	1 (17)	2 (7)	0
Nasal congestion	0	0	0	2 (33)	0	2 (7)	0
Rhinorrhea	0	0	0	2 (33)	0	2 (7)	0
Pruritis	0	0	0	1 (17)	1 (17)	2 (7)	0
Rash	0	0	0	1 (17)	1 (17)	2 (7)	0

TEAE, treatment-emergent adverse event.