

confirming ophthalmologic safety, patients are randomized (1:1) to receive HCQ or placebo for 24 months. Visits at 3 month intervals assess clinical and laboratory features and record SLICC criteria. Any participant who is found to meet SLICC classification criteria for SLE is required to exit from the trial. Biosamples are collected at each visit for measurement of autoantibody and cytokine arrays; other samples are banked for later studies.

Results Enrollment started at the beginning of 2018 and ended on July 28, 2022. At that time 256 patients had been screened and 185 enrolled into the randomized phase, slightly less than the planned enrollment of 192. The randomized participants are more than 90% female, and the average age is 33 years. The study population is predominantly White, and only 15% are Black or more than one race. A small number (5/256) screen-failed due to ophthalmologic findings. Greater than 45% of enrollees have added SLICC criteria during followup, including approximately 15% who have exited the study after achieving 4 or more SLICC criteria and thus classifying as SLE. No drug-related SAEs have been reported and treatment has not been unblinded for any participant. The last enrollee is predicted to exit the trial in mid-2024.

Conclusions The ILE definition used in SMILE targets a population in which accumulation of additional SLE criteria and transition to classifiable disease is observable within a 2 year study period. The enrolled population has a lower percentage of Black patients than anticipated, and whether this is due to a lower prevalence of the ILE stage of disease in these patients is of interest for further investigation. SMILE is generating a valuable biobank of samples for future mechanistic studies.

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Clinical Research in SLE

611 EFFICACY AND SAFETY OF NIPOCALIMAB IN ADULT PATIENTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS: DESIGN OF A PHASE 2 STUDY

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Background Autoantibody-mediated diseases, such as systemic lupus erythematosus (SLE), are caused by pathogenic antibodies that can damage tissues or organs. Approved treatments are few and associated with limitations including suboptimal response. Nipocalimab is a novel high affinity, fully human, aglycosylated, effectorless IgG1 monoclonal antibody that selectively blocks the neonatal Fc receptor (FcRn). Clinical studies conducted with nipocalimab in healthy volunteers (NCT02828046) and in adult generalized myasthenia gravis patients (NCT03896295) demonstrated rapid and durable serum IgG and pathogenic autoantibody reductions. Here we describe the protocol of a Phase 2 study evaluating the efficacy and safety of nipocalimab in patients with active SLE (NCT04882878).

Methods A phase 2, multicenter, randomized, placebo-controlled, double-blind, parallel-group study enrolling adults with active, autoantibody-positive SLE with an inadequate response to one or more standard of care treatments. The study consists of a ≤6-week screening period, a 52-week double-blind treatment period, and a 6-week follow-up period. A target of approximately 225 participants will be enrolled. Participants will be randomized in a 1:1:1 ratio to receive nipocalimab dose 1, dose 2 or placebo intravenously every 2 weeks through Week 50.

Results The primary efficacy endpoint is the percentage of participants achieving an SLE Responder Index (SRI)-4 composite response at Week 24. Secondary efficacy endpoints assessed at Week 24 include the percentage of participants achieving: ≥50% reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity score (CLASI), ≥50% reduction in active joints, ≥4 points improvement in SLE Disease Activity Index 2000 (SLEDAI 2K), and British Isles Lupus Assessment Group Composite Lupus Assessment response (BICLA); time to first disease flare; and reduction in corticosteroid use. Percentage of participants achieving an SRI-4 composite response at Week 52 will also be assessed. Safety endpoints include adverse events (AEs), serious AEs, AEs of special interest (severe infections, grade ≥3 hypoalbuminemia), and AEs leading to treatment discontinuation through Week 58. Additional assessments include pharmacokinetic, pharmacodynamic, and immunogenicity evaluations.

Conclusions This ongoing phase 2 study will evaluate the safety and efficacy of nipocalimab in adults with active SLE, using multiple clinical outcome measures.

612 SOCIAL COGNITIVE CORRELATES OF ACCELEROMETER-MEASURED AND SELF-REPORTED PHYSICAL ACTIVITY IN PERSONS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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Background/Purpose Evidence suggests that physical activity is a modifiable lifestyle behavior that helps manage the manifestations of systemic lupus erythematosus (SLE). However, persons with SLE are often physically inactive. There is a need to identify variables grounded in a well-developed theory associated with physical activity in persons with SLE, to identify correlates, targets, and behavior change strategies. This study