PO.6.136 SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): A REAL WORLD ANALYSIS SHOWING SIGNIFICANT VARIANCE IN TREATMENT PATTERNS AMONG 1,279 SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS IN THE EU5

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Purpose Systemic lupus erythematosus (SLE) patients present significant challenges in management. This study was to uncover real-world treatment patterns among moderate to severely active SLE patients in France, Germany, Italy, Spain, and the UK.

Methods 1,279 moderate and severe SLE patient records were collected in collaboration with 289 EU5 rheumatologists via an online survey platform from November 12, 2021, through January 28, 2022. Patients were at least 18 years old with diagnosed SLE and treated with at least one prescription agent.

Results While SLE treatments can be varied in the EU5 due to the diversity of the patient population, an unexpectedly high number of treatment combinations were observed among the study cohort. Close to 100 different treatment regimens were reported and a higher prevalence of polypharmacy observed in patients with more severe SLE.

Current Regimen Type Moderate Patients (n=977) | Severe Patients (n=302)

Monotherapy 37% | 28%

Dual therapy 37% | 34%

Triple therapy 20% | 29%

Quad therapy + 5% | 8%

The leading treatment among audited patients is monotherapy with HCQ; however, this only accounts for about one-tenth of all patients and is more common among those with moderate disease. Monotherapy belimumab is more prevalent among severe patients, yet these patients are typically on a wide variety of agents, frequently incorporating MTX, HCQ, and steroids.

Conclusions SLE treatment regimens are highly varied in the EU5, with disease severity playing a critical role in the treatment algorithm. Recent approval of anifrolumab in February 2022 is likely to shift the treatment approach even further as rheumatologists settle on ideal patient types for the novel Type 1 interferon inhibitor.

Disclosure Ryan Rex and Maxine Yarnall are employees of Spherix Global Insights, an independent market intelligence firm, and have received no industry funding and report on this study.

PO.6.137 DESIGN OF A PHASE 2, MULTICENTER, RANDOMIZED, PLACEBO-CONTROLLED, PARALLEL-GROUP, DOUBLE-BLIND STUDY TO ASSESS THE EFFICACY AND SAFETY OF NIPOCALIMAB IN ADULTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS

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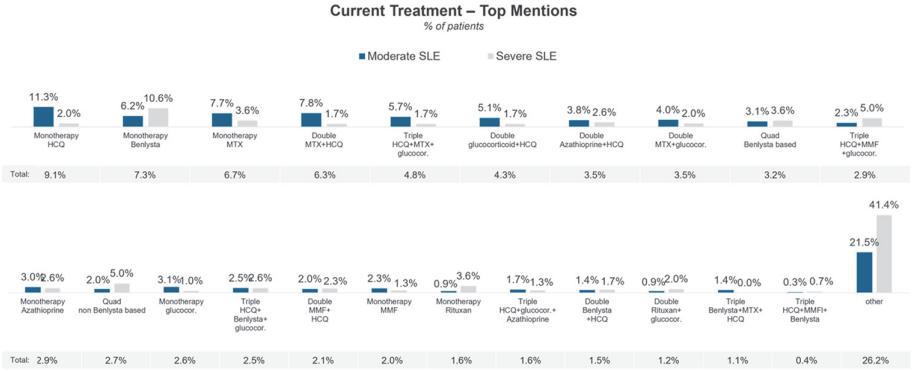
Objective Systemic lupus erythematosus (SLE) is a chronic, complex autoimmune disease characterized by pathogenic autoantibodies and tissue damage to multiple organ systems. Approved treatments are few and associated with limitations including suboptimal response for many patients. Nipocalimab is a novel high affinity, fully human, aglycosylated, effectorless IgG1 monoclonal antibody that selectively targets 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, which may be therapeutic across a broad range of autoantibody-mediated immune disorders including SLE. This abstract describes the protocol of a Phase 2 study evaluating efficacy and safety of nipocalimab in patients with active SLE (NCT04882878).

Methods This is a phase 2, multicenter, randomized, placebo-controlled, double-blind, parallel-group study enrolling adults with active, autoantibody-positive SLE with an inadequate response to ≥1 standard of care (SoC) treatments. The study consists of a ≤6-week screening period, a 52-week double-blind treatment period, and a 6-week follow-up period (figure 1). Approximately 225 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



Abstract PO.6.136 Figure 1