

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.

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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

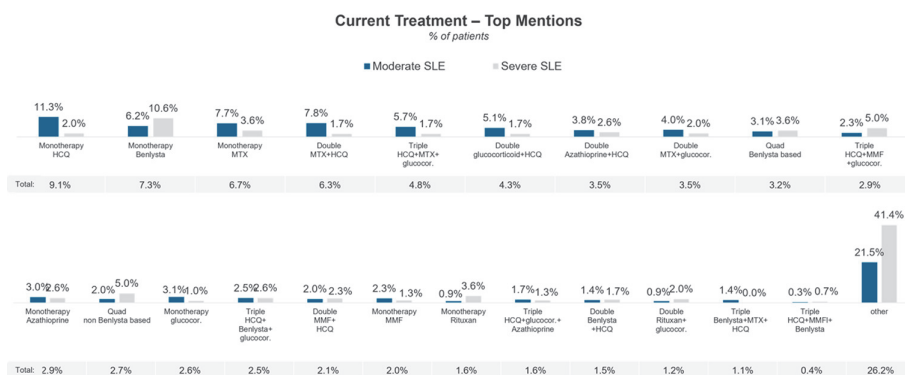
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Objective Systemic lupus erythematosus (SLE) is a chronic, complex autoimmune disease characterized by pathogenic autoantibodies and tissue damage to multiple organ systems. Approved treatments are few and associated with limitations including suboptimal 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).

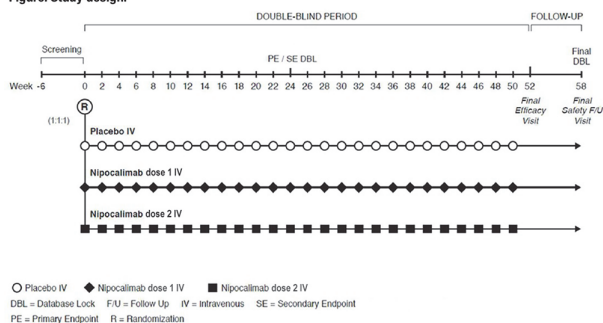
Methods This is a phase 2, multicenter, randomized, placebo-controlled, double-blind, parallel-group study enrolling adults with active, autoantibody-positive SLE with an inadequate response to ≥ 1 standard of care (SoC) treatments. The study consists of a ≤ 6 -week screening period, a 52-week double-blind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

Figure. Study design.



Abstract PO.6.137 Figure 1 Study design

assessed at Week 24 include the percentage of participants achieving: $\geq 50\%$ reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity score (CLASI), $\geq 50\%$ 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.

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

PO.6.139 EFFECT AND SAFETY PROFILE OF BELIMUMAB AND TACROLIMUS (B-T) COMBINATION THERAPY IN 33 PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A SINGLE-CENTER RETROSPECTIVE ANALYSIS

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Objective Belimumab in combination with mycophenolate mofetil has been proven to be effective for treating systemic lupus erythematosus (SLE) in several randomized controlled trials. Calcineurin inhibitors, tacrolimus, and voclosporin are also useful in controlling the activity of lupus nephritis. However, the safety and effectiveness of belimumab-calcineurin inhibitor combination therapy has not been addressed. Therefore, we conducted a single-center retrospective study to analyze the safety and efficacy profile of belimumab-tacrolimus (B-T) combination therapy in patients with SLE.

Methods Patients with SLE administered tacrolimus and belimumab during the course of treatment were included in the study, and samples collected were analyzed for the drug retention rate, SLE flare rate, infection incidence rate, and glucocorticoid-sparing effect of the B-T combination therapy.

Results In total, 33 patients with SLE were treated with B-T combination therapy at our institution. Four patients discontinued the treatment because of insufficient response/adverse events. The drug retention rate was more than 90% at week 52 and approximately 80% at day 1000. Only one patient developed serious infection.

The LLDAS achievement ratio was 9.1% on the day of initiation, and improved to 63.3% at week 26 and to 64.0% at 52 weeks after initiation.

SLE flares were observed in only 3 patients (9.1%) in the first 52 weeks after initiation, and in 5 patients (15.2%) throughout the study period. A glucocorticoid-reducing effect was also observed in patients treated with B-T combination therapy.

Conclusion In most patients with SLE, B-T combination therapy was well-tolerated, and showed a good efficacy profile and glucocorticoid reducing effect. Thus, B-T combination therapy can be a feasible option for patients with refractory lupus.

PO.6.140 TREATMENT PATTERN OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A COHORT STUDY AT RHEUMATOLOGIST PRACTICES IN GERMANY

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Purpose Patients with lupus are chronically exposed to anti-inflammatory and immunosuppressive treatments that are associated with considerable morbidities. This study aimed to describe treatment patterns of systemic lupus erythematosus (SLE) patients in Germany.

Methods One cohort of SLE patients who were diagnosed between 2001 and 2019 and treated at primary care rheumatologist practices were selected in the German IQVIA Disease Analyzer. This database provides anonymized data on prescriptions directly from the participating practice's computer systems. Patients were followed from the first recorded diagnosis until the earliest of their last visit or September 2020. Prescriptions were described with percentages calculated based on the number of patients with ≥ 1 visit during yearly time intervals.

Results A total of 423 SLE patients were included. The median (Q1, Q3) follow-up was 4.2 (1.6, 8.1) years. Median age was 50 years and 85% were female. Glucocorticoids (GCs) were the most prescribed treatments in the first 5 years following diagnosis with SLE (52–70% of patients prescribed oral GCs per year). Antimalarials and immunosuppressants were the second most prescribed treatments: antimalarials (32–39%), azathioprine (15–17%), methotrexate oral (7–10%) or subcutaneous (4–7%), and mycophenolate (5–7%). Biologics (e.g., belimumab, rituximab, tocilizumab) were prescribed for <4% of patients. Opioids were prescribed for 5–8% of patients. A trend towards decreased use of GCs was observed in SLE patients diagnosed between 2015 and 2019 versus patients diagnosed between 2001 and 2009 (47–64% vs 44–74%). Use of opioids also decreased (2–5% vs 6–13%). Biologics use remained limited (3–4% vs 0–5%).

Conclusions In primary care rheumatologist practices in Germany, GCs remain the cornerstone treatment for SLE although there is a trend of decreased usage, antimalarials are also widely used, as well as immunosuppressants. Biologic treatments are used infrequently. Pain management