after being treated with rituximab (500mg d 0) plus bortezomib (2.5mg d 1, 4, 8, 11), the immune status of the patient was improved gradually and all indexes returned to normal ranges. Half a year later, rituximab (100mg d 0) plus bortezomib (2.5mg d 1, 4, 8, 11) was applied. Ultimately, the patient was in remission without recurrence until now. Additionally, we summarized the available literature and explained the possible mechanism. Rituximab combined with bortezomib was more effective for depleting B cells and plasmocytes, which was accompanied by decreases in antibodies. Finally, although there were no adverse effects in this patient, we pointed out that rituximab plus bortezomib might cause infection and peripheral neuropathy. Therefore, monitoring safety is required.

Conclusions Our case shows that rituximab combined with bortezomib is effective in treating SLE patients with refractory hemolytic anemia, but safety should be monitored.

LP-191 BASELINE PROFILE OF SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS ON TREATMENT WITH BELIMUMAB OF A SPANISH MULTICENTER COHORT

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Background Baseline profile of systemic lupus erythematosus patients on treatment with Belimumab of a Spanish multicenter cohort.

Methods Multicenter retrospective and longitudinal cohort study. Data was collected at baseline, 6, 12 months and in the last visit available. Different periods (2010–2015/2016–2021) were compared.

Results 324 patients (91% female) were enrolled. Mean (±SD) age at diagnosis: 31.8 years (±11.9); mean disease duration of 8.7 years (±9.07). At baseline, mean SLEDAI-2K score was 10.4 (±5.25); 152 (47.5%) patients had damage with a mean SDI score of 0.83 (±1.2). 289 patients (89.2%) had received DMARDs before BLM: cDMARDS in 282 (87%) and bDMARDs in 74 patients (22.8%); 164 (51.9%) had received more than one cDMARDs, methotrexate being the most frequently used (44.4%) and Rituximab the most frequent bDMARDs used (80%). Antimalarials were used in 83,2% and glucocorticoids (GC) in 91.2%, with a mean dose of 12.3 mg/day. 67.9% of patients were receiving more than 5 mg/day and 58.4% more than 7.5 mg/day of prednisone. BLM was used in monotherapy in 30.5% of subjects. Reasons of prescription: disease activity in 95% of patients and/or as a GC sparing agent in 59%. Only a few patients received BLM just for maintenance (4/322) or save GC (8/322). At baseline, 6 patients (1.9%) were in DORIS-21-remission and LLDAS. The main reasons of prescription for ongoing activity were arthritis (65.4%), cutaneous (40.7%) or both (81%). No differences were observed in prescription reasons between periods.

Conclusions Belimumab was mainly prescribed after the use of other DMARDs and more than 50% had received at least 2 DMARDs and were receiving GC at medium doses. Most patients received BLM due to active disease and/or as GC sparing agent. Activity in articular and cutaneous domains were the main reasons of indication. No changes in prescription habits were identified.

LP-195 DESIGN OF A PHASE 2 STUDY EVALUATING THE EFFICACY AND SAFETY OF NIPOCALIMAB IN ADULT PATIENTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS

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Background Systemic lupus erythematosus (SLE) is a chronic, complex autoimmune disease characterized by pathogenic autoantibodies and tissue damage to multiple organ systems. Nipocalimab is a novel high affinity, fully human, aglycosylated, effectorless IgG1 monoclonal antibody that selectively blocks the neonatal Fc receptor (FcRn). Nipocalimab has demonstrated rapid and durable serum IgG and pathogenic autoantibody reductions (NCT02828046; NCT03896295). Here we describe the protocol of a Phase 2 study evaluating the efficacy and safety of nipocalimab in patients with active SLE (NCT04882878).

Methods 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 (figure 1). 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