LP-184 RATIONALE AND DESIGN OF TWO PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDIES OF THE EFFICACY AND SAFETY OF LITIFILIMAB IN ADULTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS: TOPAZ-1 AND TOPAZ-2

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Background Litifilimab is a humanized IgG1 monoclonal antibody targeting BDCA2, a receptor predominantly expressed on plasmacytoid dendritic cells (pDCs). In Part A of the Phase 2 LILAC study (NCT02847598), administration of litifilimab at a dose of 450 mg was superior to placebo in reducing the total active joint count at Week 24 and resulted in a greater frequency of SLE Responder Index 4 (SRI-4) responses versus placebo.[1] Two multicenter, Phase 3, randomized, double-blind, placebo-controlled studies (TOPAZ-1, NCT04895241; TOPAZ-2, NCT04961567), described here, are ongoing to further evaluate litifilimab efficacy and safety in patients with SLE.

Methods Eligible participants are randomly assigned to receive either subcutaneous litifilimab (at a high or low dose) or placebo at Weeks 0 and 2, then Q4W until Week 48 (figure 1). Appropriate representation of individuals from underrepresented populations is a focus of the TOPAZ program. The SRI-4 response at Week 52 was chosen as the primary endpoint based on its performance in Part A of the LILAC study. Multiplicity-adjusted secondary endpoints of TOPAZ-1/-2 include Joint-50 response (a 50% reduction from baseline in the active joint count, where an active joint is defined as both swollen and tender, based on a 28-joint assessment) and oral corticosteroid (OCS) tapering. Additional secondary endpoints include the Cutaneous Lupus Erythematosus Disease Area and Severity Index-Activity score, Lupus Low Disease Activity State, and safety. Key features of this study design are the inclusion of several organ-specific evaluations, stringent rules for concomitant medication, and protocol-specified OCS tapering.

Results Both studies are currently recruiting, aiming to enroll 540 participants each; estimated primary completion dates are April 2025 (TOPAZ-1) and June 2025 (TOPAZ-2).

Conclusions Data from the TOPAZ studies will help characterize the efficacy and safety of litifilimab in SLE, a disease in need of greater treatment options.

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LP-185 TREATMENT OF CUTANEOUS LUPUS ERYTHEMATOSUS WITH ENERGY BASED DEVICES

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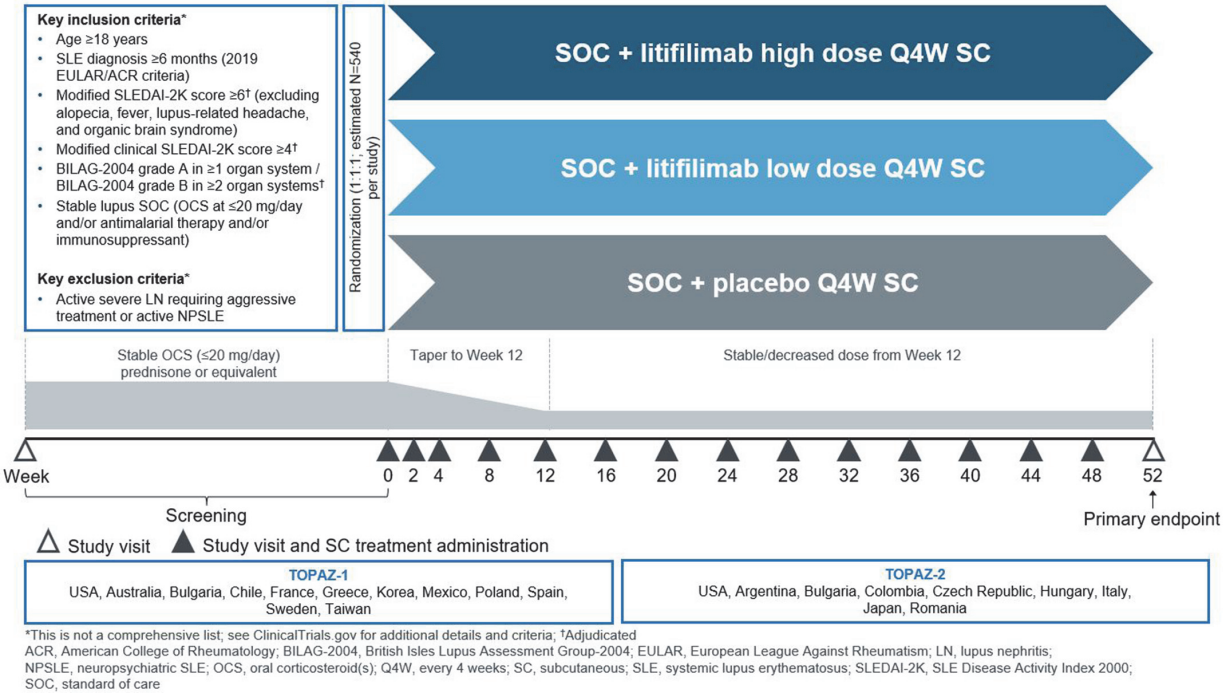
Background Current mainstay treatment of cutaneous lupus erythematosus (CLE) include topical corticosteroids, sun protection, and systemic treatment. Various non-medical



Abstract LP-184 Figure 1 TOPAZ-1 and TOPAZ-2 study design

alternative/adjunctive treatment have been reported such as cryotherapy, and laser therapy. Several studies have shown the efficacy of pulsed dye laser (PDL) for discoid lupus erythematosus (DLE). Additionally, there was a case report showing the efficacy of fractional photothermolysis for reminiscent scar of DLE.

Methods This was a retrospective study which included 20 CLE patients who visited the Department of Dermatology at Hanyang University Seoul Hospital in Korea between November 2016 and December 2022. Patient medical datas and clinical photographs were reviewed.

Results Of the 20 CLE patients, 15 (75%) underwent PDL, 7 (35%) underwent fractional laser, 9 (45%) underwent long-pulse neodymium-doped yttrium aluminium garnet (Nd:YAG), 4 (20%) underwent 532-nm Nd: YAG, and 2 (10%) were treated with intense pulsed light (IPL). The majority of patients had been taking hydroxychloroquine for several years. After a mean number of 2.4 sessions of PDL, patients showed improvement of telangiectasias and erythema, and there was mild improvement of atrophic and pigmented lesions. After a mean number of 3.1 sessions of fractional laser, there was improvement of scarring lesions of DLE. All treatments were well tolerated, and all patients did not show any worsening of disease. Also, none of our patients experienced any long-lasting side effects, such as photosensitivity, disease reactivation, or pigmentary defects.

Conclusions In general, laser treatments are still regarded as harmful in patients with underlying immunologic deficiency or autoimmune connective tissue disorder, since wound healing in these patients may be impaired. None of our patients, however, showed any worsening of skin lesion or side effects. It seems reasonable and safe to use laser treatments as an adjunctive treatment for cosmetic purpose to patients who achieve stable disease activity.

LP-186 INITIAL EXPERIENCE WITH BELIMUMAB IN SE ASIAN LUPUS PATIENTS – A REPORT OF 6 PATIENTS

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Background Belimumab, a human IgG1 monoclonal antibody, inhibits the binding of soluble B lymphocyte stimulator to B cells. It is approved for renal and non-renal SLE and as an add-on therapy. Belimumab was only made available in Singapore in Jan 2022, and we hope that it will be a potential disease-modifying and disease-remitting lupus biologic therapy.

Methods We reviewed and analysed our initial experience with belimumab therapy in 6 SLE patients as an add-on and/or sequential therapy after rituximab since the start of Jan 2022 till Jan 2023

Results All 6 patients were female, age range 21–64 years old, with 3 Chinese, 1 Malay, and 2 Cambodian. Disease duration ranged from few months to 4 years. 2 had renal

Involvement, and one patient has SLE/APS.

Concomitant medications includes prednisolone(6 patients). tacrolimus(4 patients), mycophenolate (2 patients), baricitinib (4 patients), hydroxychloroquine (4 patients). 3 patients had sequential rituximab -belimumab therapy.

IV belimumab infusion was very well tolerated without any adverse events

Number of infusions completed ranged from 2–11(average 7).

Disease stability, reduction of steroid doses and severity of flares were observed in this small case series of patients.

Conclusions Belimumab is a useful disease-modifying and disease-remitting therapy that can be added-on to the standard lupus therapy with minimal adverse effects. More patients and longer follow-up period will be needed to gain a wider clinical patient experience.

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LP-187 ABSTRACT WITHDRAWN