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

Ronald F Van vollenhoven*, Richard A Furie, Eric F Morand, Kenneth Kalunian, Maria Dallerera, Stacey Goode-sellers, Puja Joshi, George Kong, Ting Wang, Youmna Lahoud, Catherine Barbey, Department of Rheumatology and Clinical Immunology, Amsterdam University Medical Centers, Amsterdam, Netherlands; Division of Rheumatology, Northwell Health, Great Neck, NY, USA; School of Clinical Sciences, Monash University, Victoria, Australia; Division of Rheumatology, Allergy and Immunology, University of California San Diego, CA, USA; Division of Rheumatology, University of California San Francisco, CA, USA; Research and Development, Biogen, Cambridge, MA, USA; MS Immunology Clinical Development, Biogen, Cambridge, MA, USA; MS-Immunology Development Unit, Biogen, Cambridge, MA, USA; MS-Immunology Development Unit, Biogen, Baar, Switzerland.

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 Erythematous 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.

REFERENCE

TREATMENT OF CUTANEOUS LUPUS ERYTHEMATOSUS WITH ENERGY BASED DEVICES

Jin Hyun Jang*, Yun Jung Huh, Ki Yeon Kim, Mihn Sook Jue, Jeong Eun Kim, Joo Yeon Ko.

Department of Dermatology, Hanyang University College of Medicine, Seoul, Korea, Republic of Korea

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