



LFA's Center for Clinical Trials Education (CCTE)

Spotlight on:



Study Title: A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study of the Efficacy and Safety of Four 12-week Treatment Cycles (48 Weeks Total) of Epratuzumab in Systemic Lupus Erythematosus Subjects with Moderate to Severe Disease

Sponsor: UCB, Inc.

Purpose: To confirm the clinical efficacy of epratuzumab in the treatment of subjects with Systemic Lupus Erythematosus (SLE)

Eligibility criteria: Men and women, at least 18 years old

Key Inclusion Criteria - Individuals may be eligible if they are:

- Diagnosed with systemic lupus erythematosus
- Available for 27 study visits over a period up to 1 year

Key Exclusion Criteria - Individuals may be excluded if they:

- Are breastfeeding, pregnant, or plan to become pregnant
- Have active, severe SLE disease activity which involves the renal system
- Have active, severe neuropsychiatric SLE
- Are in an immunosuppressive state
- Have a history of malignant cancer, except the following treated cancers: cervical carcinoma in situ, basal cell carcinoma, or dermatological squamous cell carcinoma
- Have a history of infections, including but not limited to concurrent acute or chronic viral hepatitis B or C
- Have received treatment with other anti-B cell antibodies within 12 months prior to screening (visit 1)

Study Type: Interventional - Participants will receive study treatment with the investigational study drug or an inactive placebo up to 16 times. The investigational study drug or placebo will be administered by intravenous infusion. Each infusion will last about 1 hour.

Locations: 30 physician offices for EMBODY 1 and 30 physician offices for EMBODY 2 throughout the United States.

Contact: www.EmbodProgram.com

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