BEconneCTD-ILD

A Phase 3, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of belimumab administered subcutaneously in adults with interstitial lung disease associated with connective tissue disease

Dear _____,

There continues to be a need for better treatment options for patients with interstitial lung disease (ILD) associated with connective tissue disease (CTD), a condition that places a considerable burden on patients and healthcare resources.

Belimumab is a monoclonal antibody approved for the treatment of systemic lupus erythematosus that, through binding B lymphocyte stimulator (BLyS), has been shown to inhibit the survival of B cells and reduce differentiation into IgG-producing plasma cells. B cells have been reported to play a central role in the pathogenesis of ILD, and B-cell depletion has been shown to improve lung function in patients with CTD-ILD.[1,2] We hypothesize that modulating the B-cell compartment towards a more regulatory B-cell profile with belimumab will lead to reduced inflammation and fibrosis across multiple organ systems.

GSK is currently sponsoring a clinical research study to investigate the efficacy and safety of belimumab for the treatment of patients with CTD-ILD receiving standard therapy. Based on its mechanism of action, proven efficacy in the treatment of SLE and LN, as well as its established safety profile, belimumab is expected to improve/stabilize lung function decline, slow ILD progression, and have a positive effect on symptoms such as dyspnea, cough, and fatigue.

Please refer to the opposite side of this letter for more information on the study or visit the trial listing on ClinicalTrials.gov [placeholder for NCT#].

Do you have eligible patients?

Please consider referring them to this study. If you or your patient have additional questions, please call the BEconneCTD-ILD Study staff at:

_____

_____.

Thank you for your consideration.
Sincerely,

_____

By referring patients, you are neither requiring them to participate, nor guaranteeing their enrollment.

Patients enrolled in the study can remain in your care during their participation.

Scan the code or visit [**studywebsite.com**].

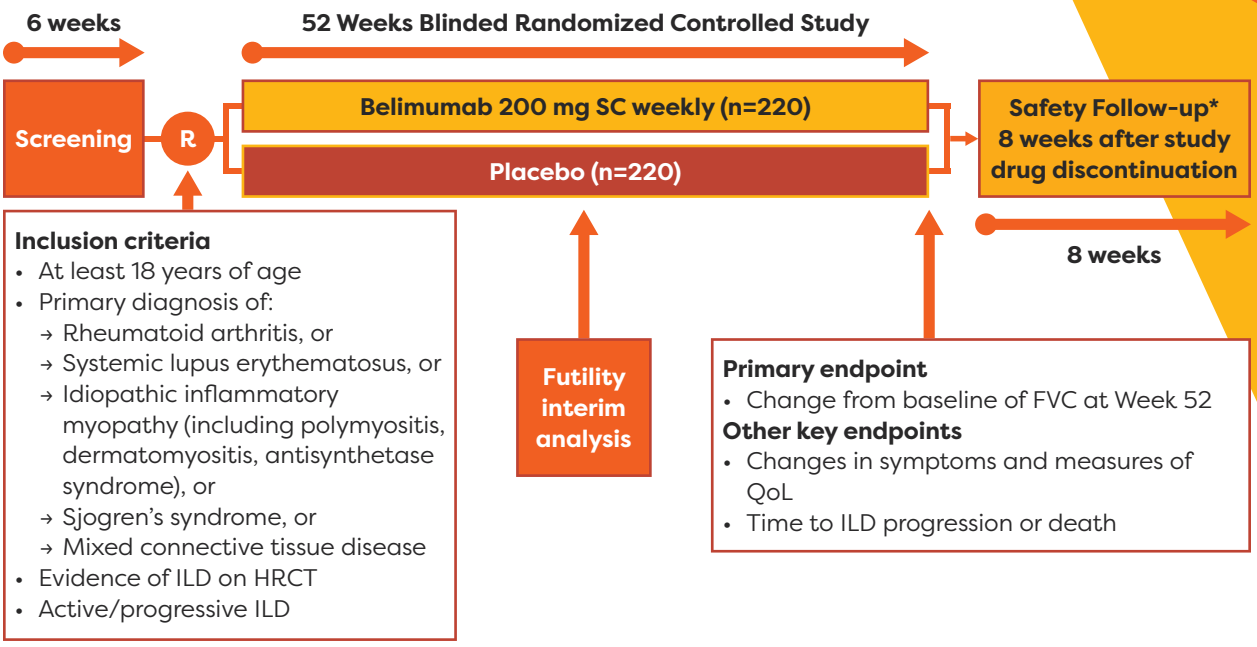
[QR]

GSK - BEconneCTD-ILD - HCP Letter - 16-JUL-2024 - English (Principal) - V1.0

BEconneCTD-HCP-EnP

Study Design

Approximately 440 participants will be randomized to receive belimumab or the placebo (1:1) in addition to standard therapy.



FVC = forced vital capacity; HRCT = high-resolution computed tomography; IgG = immunoglobulin; LN = lupus nephritis; QoL = quality of life; SC = subcutaneous; SLE = systemic lupus erythematosus.

*Participants who complete the Week 52 visit and have not been classified as a treatment failure will be eligible to join a separate Open-Label Extension Study (Study 221949) and receive open-label treatment with belimumab 200 mg SC weekly.

Permitted Concomitant Medication for CTD-ILD

Standard therapy can include the following, alone or in combination, in accordance with current treatment guidelines and local labels:

- Oral corticosteroids (≤20 mg/day oral prednisolone or equivalent) at a stable dose for at least 30 days
- Mycophenolate mofetil ≤3000 mg/day or mycophenolate sodium ≤2160 mg/day, at a stable dose for at least 180 days
- Methotrexate ≤25 mg/week, at a stable dose for at least 90 days prior
- Azathioprine ≤2.5 mg/kg/day, at a stable dose for at least 90 days prior
- Tacrolimus ≤2.5 mg daily (a higher dose of 5 mg daily is allowed if the locally approved or recommended dose is higher than 2.5 mg daily), at a stable dose for at least 90 days
- Cyclosporin ≤4 mg/kg daily, at a stable dose for at least 90 days
- Hydroxychloroquine ≤400 mg/day, at a stable dose for at least 90 days
- Leflunomide ≤20 mg/day at a stable dose for at least 90 days

References:
1. Bagnato G, Harari S. *Eur Respir Rev.* 2015;24(135):102-114.
2. Maher TM, Tudor VA, Saunders P, et al. *Lancet Respir Med.* 2023;11(1):45-54.