

A Study of the Efficacy and Safety of Belimumab in Adults With Interstitial Lung Disease Associated With Connective Tissue Disease

NCT06572384

Status	RECRUITING
Phase	Phase 3
Sponsor	GlaxoSmithKline
Enrollment	440 participants

Key Eligibility Criteria

Inclusion (10)

- Participants with persistent/worsening active inflammatory disease who have failed to achieve their treatment goal, i. e., those who have experience lack of expected treatment benefit (clinically meaningful improvement in FVC), fail to demonstrate sustained lung function stability or continue to experience worsening of ILD despite initiation of standard therapy or failed to tolerate standard therapy.
- Documented diagnosis of rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), idiopathic inflammatory myopathy (IIM; including polymyositis, dermatomyositis, anti-synthetase syndrome), Sjogren's syndrome (pSS), or mixed connective tissue disease (MCTD) in accordance with internationally recognized classification criteria
- Diagnosis of inflammatory and/or fibrotic ILD on High Resolution Computed Tomography (HRCT) with a total disease extent of greater than or equal to (e) 10% of the whole lung
- Evidence of persistent active/worsening ILD
- Must be currently receiving stable standard therapy to manage ILD and/or underlying CTD, or to have failed or failed to tolerate standard therapy.

... and 5 more (see full listing online)

Exclusion (16)

- Diagnosis of ILD other than CTD-ILD.
- Primary diagnosis of Systemic Sclerosis (SSc).
- Participants with rapidly progressive disease (absolute drop of 10% or more of FVC between screening and baseline visit and/or recent pulmonary hospitalization).
- FVC \leq 45% of predicted, or a Diffusing Capacity of the lung for Carbon Monoxide (DLco) (corrected for hemoglobin) \leq 40% of predicted at screening as confirmed by central reader
- History or presence of diffuse alveolar hemorrhage (DAH) or other confounding pulmonary disease, signs, or symptoms

... and 11 more (see full listing online)

Locations (131 total)

GSK Investigational Site, Los Angeles, California, United States
GSK Investigational Site, Los Angeles, California, United States
GSK Investigational Site, Los Angeles, California, United States
... and 128 more locations

<https://clinicaltrials.gov/study/NCT06572384>

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