

A Study of the Efficacy and Safety of Belimumab in Adults With Systemic Sclerosis Associated Interstitial Lung Disease

NCT05878717

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	GlaxoSmithKline
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (12)

- Participant is 18 years of age inclusive, or older at the time of signing the informed consent.
- Documented diagnosis of SSc as defined by the American College of Rheumatology / European League Against Rheumatism 2013 SSc classification criteria.
- Diffuse cutaneous disease, defined as presence of thickened skin with mRSS ≥ 0 over at least one skin area proximal to elbows and/or knees in addition to distal areas involvement on Day 1.
- Total mRSS ≤ 15 on Day 1.
- Evidence of interstitial lung disease on centrally read screening HRCT.
- ... and 7 more (see full listing online)

Exclusion (16)

- Systemic sclerosis-like illness, including but not limited to localized scleroderma (morphoea), eosinophilic fasciitis, sclerodermoid graft-versus-host disease, fibro mucinous conditions (scleroedema, scleromyxoedema), scleroderma-like conditions that are associated with environmental chemical and drug exposure (e.g., toxic rapeseed oil, vinyl chloride, bleomycin, gadolinium-based contrast agents [nephrogenic systemic fibrosis]), or due to metabolic disease).
- Primary diagnosis of a rheumatic autoimmune disease other than dcSSc, including but not limited to rheumatoid arthritis, systemic lupus erythematosus, polymyositis, dermatomyositis, systemic vasculitis, Sjogren's syndrome, antisynthetase syndrome, or mixed connective tissue disease, as determined by the investigator.
- FVC $\geq 45\%$ of predicted, or a DLco (corrected for hemoglobin) $\geq 40\%$ of predicted or requiring supplemental oxygen at screening.
- Pulmonary arterial hypertension, as determined by the investigator at, or prior to first day of dosing (Day 1).
- SSc renal crisis within 6 months prior to the first day of dosing (Day 1).
- ... and 11 more (see full listing online)

Locations (131 total)

GSK Investigational Site, Phoenix, Arizona, United States
GSK Investigational Site, Scottsdale, Arizona, United States
GSK Investigational Site, Scottsdale, Arizona, United States
... and 128 more locations