

A Study to Investigate the Long-term Safety and Efficacy of Belimumab in Adults With Interstitial Lung Disease (ILD) Associated With Systemic Sclerosis (SSc) and Other Connective Tissue Diseases (CTD) (BLISSconneCTD-OLE)

NCT06716606

Status	RECRUITING
Phase	Phase 3
Sponsor	GlaxoSmithKline
Enrollment	514 participants

Key Eligibility Criteria

Inclusion (11)

- Participants with SSc-ILD or other CTD-ILDs that have completed either study 218224 or 221672 through to and including the Week 52 visit and are not considered treatment failure, defined as meeting either of the following criteria:
- Discontinuation of study medication during study 218224 or 221672 for any reason.
- Participants with SSc should have an area of uninvolved or mildly thickened skin that, in the opinion of the investigator, would allow subcutaneous (SC) injection at the abdomen or the front, middle region of the thigh.
- Participant is capable and willing to self-administer the study medication or has a caregiver/healthcare professional who is capable and willing to administer the study medication throughout the study.
- Female participants: A female participant is eligible to participate if she is not pregnant or breastfeeding, and one of the following conditions applies:
... and 6 more (see full listing online)

Exclusion (5)

- Participants of study 218224 or study 221672 who have discontinued study treatment, prior to Week 52.
- Participants who have developed clinical evidence of significant, unstable or uncontrolled, acute or chronic diseases not due to SSc or other CTD (i.e, cardiovascular, pulmonary, hematologic, gastrointestinal, hepatic, renal, neurological, malignancy or infectious diseases), or experienced an AE in study 218224 or study 221672 that could, in the opinion of the principal investigator, put the participant at undue risk.
- Participants who have developed any other medical diseases (eg, cardiopulmonary), laboratory abnormalities, or conditions (eg, poor venous access) that, in the opinion of the investigator could significantly alter the absorption, metabolism, or elimination of drugs; constitutes a risk when taking the study intervention; interferes with the interpretation of data; or it is not safe for the participant to continue on the study.
- Participants who have been exposed to ionizing radiation in excess of 10 millisievert (mSv) above background over the previous 3 year period as a result of occupational exposure or previous participation in research studies.
- QT Interval Corrected (QTc) greater than (>) 480 millisecond (msec) at Week 52 of parent study 218224 or study 221672.

Locations (10 total)

GSK Investigational Site, Philadelphia, Pennsylvania, United States
GSK Investigational Site, Ciudad Autonoma Buenos Aires, Argentina
GSK Investigational Site, Ciudad Autonoma de Buenos Aire, Argentina
... and 7 more locations

<https://clinicaltrials.gov/study/NCT06716606>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.