

A Study to Assess the Efficacy and Safety of Efgartigimod PH20 SC in Adults With Systemic Sclerosis

NCT06655155

Status	RECRUITING
Phase	Phase 2
Sponsor	argenx
Enrollment	81 participants

Key Eligibility Criteria

Inclusion (7)

- Is aged ≥18 years and the local legal age of consent for clinical studies
- Has diffuse or limited SSc diagnosis and fulfills the 2013 ACR/EULAR classification criteria
- Has a positive antinuclear antibodies (ANA) test result at the central laboratory with titer of at least 1:160
- Has a Health Assessment Questionnaire-Disability Index (HAQ-DI) score of at least 0.5 OR a Patient Global Assessment (PGA) score of at least 3
- Has a modified Rodnan Skin Score (mRSS) score between 15 and 35
- ... and 2 more (see full listing online)

Exclusion (6)

- Isolated anticentromere antibodies (ACA) seropositivity at the central laboratory
- Significant Pulmonary Arterial Hypertension
- Severe digital vasculopathy within the past 3 months
- Skin thickening due to scleroderma mimics or localized scleroderma
- Scleroderma renal crisis within the past 6 months of participating to the study
- ... and 1 more (see full listing online)

Locations (69 total)

Arizona Arthritis and Rheumatology Associates, Phoenix, Arizona, United States
UCLA Ronald Reagan University of California Los Angeles Medical Center, Los Angeles, California, United States
IRIS Research and Development LLC, Plantation, Florida, United States
... and 66 more locations