

A Study of the Efficacy and Safety of Efgartigimod in Patients With Primary Sjögren's Syndrome

NCT06684847

Status	RECRUITING
Phase	Phase 3
Sponsor	argenx
Enrollment	580 participants

Key Eligibility Criteria

Inclusion (2)

- Is at least 18 years of age and the local legal age of consent for clinical studies when signing the ICF.
- Meets the following criteria at screening: fulfilled ACR/EULAR classification criteria 2016 pSjD criteria before screening; clinESSDAI e 6 at screening; Anti-Ro/SS-A positive at central laboratory; Unstimulated residual salivary flow (e 0.01 mL/min)

Exclusion (5)

- Secondary (also referred to as associated) Sjögren's disease, defined as overlap with another autoimmune rheumatic or systemic inflammatory condition (eg, rheumatoid arthritis, systemic lupus erythematosus, scleroderma, or idiopathic inflammatory myopathy)
- Active fibromyalgia which is not adequately controlled in the judgment of the investigator, or participant is receiving fibromyalgia treatment that has not been stable treatment for at least 12 weeks before screening.
- Any severe systemic pSjD manifestation that is not adequately controlled at screening or baseline that may put the participant at undue risk based on the investigator's opinion.
- Use of cyclophosphamide d 24 weeks prior to screening
- Anti-CD20 or anti-CD19 antibody received \< 6 months before screening

Locations (304 total)

One of a Kind Clinical Research Center LLC, Scottsdale, Arizona, United States
Arizona Arthritis & Rheumatology Research, PLLC, Sun City, Arizona, United States
Arizona Arthritis & Rheumatology Research, PLLC, Tucson, Arizona, United States
... and 301 more locations