

A Repeated Dose-finding Study of Sarilumab in Children and Adolescents With Systemic Juvenile Idiopathic Arthritis (SKYPS)

NCT02991469

Status	RECRUITING
Phase	Phase 2
Sponsor	Sanofi
Enrollment	51 participants

Key Eligibility Criteria

Inclusion (3)

- Male and female patients aged e1 and d17 years (or country specified age requirement, e6 to d17 years for Russia) at the time of the screening visit.
- Diagnosis of systemic JIA subtype according to the International Associations against Rheumatism (ILAR) 2001 Juvenile Idiopathic Arthritis (JIA) Classification Criteria OR According to 2024 EULAR/PReS recommendation at Screening.
- Patient with an inadequate response to current treatment and considered as a candidate for a biologic disease modifying anti rheumatic drug (DMARD) as per investigator's judgment.

Exclusion (18)

- Body weight $\lt 10$ kg or $\gt 60$ kg for patients enrolled in the ascending dose cohorts, then body weight $\lt 10$ kg for patients subsequently enrolled at the selected dose.
- Uncontrolled severe systemic symptoms and/or Macrophage Activation Syndrome (MAS) within 6 months prior to screening.
- History of or ongoing interstitial lung disease, pulmonary hypertension, pulmonary alveolar proteinosis.
- If nonsteroidal anti-inflammatory drugs (NSAIDs) (including cyclo oxygenase-2 inhibitors \backslash [COX-2 \backslash]) taken, dose stable for less than 2 weeks prior to the baseline visit and/or dosing prescribed outside of approved label.
- If non-biologic DMARD taken, dose stable for less than 6 weeks prior to the baseline visit or at a dose exceeding the recommended dose as per local labeling.

... and 13 more (see full listing online)

Locations (29 total)

Investigational Site Number : 0320004, San Miguel de Tucumán, Tucumán Province, Argentina

Investigational Site Number : 1240110, Calgary, Alberta, Canada

Investigational Site Number : 2460040, Helsinki, Finland

... and 26 more locations

<https://clinicaltrials.gov/study/NCT02991469>

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