ForPatients
by Roche

Juvenile Idiopathic Arthritis

A Study of Tocilizumab in Chinese Participants With Systemic Juvenile Idiopathic Arthritis (sJIA)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03301883 YA39368

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase IV, Multicenter, Single-Arm, Open-Label Study to Assess the Efficacy and Safety of Tocilizumab in Chinese Patients With Systemic Juvenile Idiopathic Arthritis

Trial Summary:

This Phase IV, multicenter, single-arm, open-label study will evaluate the efficacy and safety of tocilizumab in Chinese participants with sJIA with persistent activity and an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) and steroid therapy.

Hoffmann-La Roche	Phase 4
Sponsor	Phase

NCT03301883 YA39368
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 2 Years & # 17 Years	No

Inclusion Criteria:

- Participants meeting International League of Associations for Rheumatology (ILAR) classification for sJIA
- Greater than (>) 6 months of documented persistent sJIA activity prior to screening
- Active disease
- hsCRP >4.3 milligrams per liter (mg/L) or 0.43 milligrams per deciliter (mg/dL)

- Participant who has recovered from any symptomatic serositis for at least 30 days prior to the screening visit, and requires a dose of CSs at baseline of </=30 mg/day or </=0.5 mg/kg/day, whichever is less
- Participants meeting one of the following: Participant who is not receiving MTX or discontinued MTX >/=4 weeks prior to baseline visit; participant who has been taking MTX >/=12 weeks immediately prior to the baseline visit and on a stable dose of </=20 mg/m^2 for >/=8 weeks prior to the baseline visit, together with either folic acid or folinic acid according to local standard of care
- Participant who was never treated with biologics or, if was previously treated with biologics, discontinued etanercept (or Yisaipu, Qiangke, or Anbainuo) >/=2 weeks, infliximab or adalimumab >/=8 weeks, anakinra >/=1 week, or abatacept >/=12 weeks prior to the baseline visit
- Participant who is not currently receiving oral CSs, or is taking oral CSs at a stable dose for >/=2 weeks prior to the baseline visit at </=30 mg/day or </=0.5 mg/kg/day, whichever is less
- Participant who is not taking NSAIDs, or taking </=1 type of NSAID at a stable dose for >/=2 weeks prior to the baseline visit and is less than or equal to the maximum recommended daily dose

Exclusion Criteria:

- Wheelchair bound or bedridden participant
- Any other autoimmune, rheumatic disease, or overlap syndrome other than sJIA
- Participant who is not fully recovered from recent surgery or <6 weeks since surgery at the time of screening visit; or planned surgery during the initial 12 weeks of the study
- Lack of peripheral venous access
- Any significant concurrent medical or surgical condition that would jeopardize the participant's safety or ability to complete the trial
- Evidence of serious uncontrolled concomitant diseases
- Asthma for which the participant has required the use of oral or parenteral CSs for >/=2 weeks within 6 months prior to the baseline visit
- Known human immunodeficiency (HIV) infection or other acquired forms of immune compromise or congenital conditions characterized by a compromised immune system
- Any active acute, subacute, chronic, or recurrent bacterial, mycobacterial, viral, or systemic fungal infection or opportunistic infection
- Any major episode of infection requiring hospitalization or treatment during screening, treatment with IV antibiotics completing within 4 weeks of the screening visit, or oral antibiotics completing within 2 weeks of the screening visit
- History of atypical tuberculosis (TB)
- Active TB requiring treatment within 2 years prior to screening visit
- Positive purified protein derivative (PPD) or T-spot test (interferon-gamma [IFN-#]-based test) at screen
- Positive for latent TB
- History of reactivation or new onset of a systemic infection such as herpes zoster or Epstein-Barr virus (EBV) within 2 months of the screening visit
- Hepatitis B surface antigen (Ag)- or hepatitis C antibody (Ab)-positive
- History of macrophage activation syndrome (MAS) within 3 months prior to the screening visit
- Evidence of active malignant disease or diagnosed malignancies
- Uncontrolled diabetes mellitus
- Previous treatment with tocilizumab
- Intra-articular, intramuscular, IV, or long-acting CSs administration within 28 days prior to the baseline visit
- Treatment with non-biologic disease-modifying antirheumatic drugs (DMARDs; other than MTX) within 6 weeks prior to the baseline visit
- Treatment with leflunomide that was not followed by standardized cholestyramine washout and documented to be below the limit of detection prior to the baseline visit

- Treatment with cyclophosphamide, etoposide (VP16) and statins within 90 days prior to the baseline visit
- Treatment with growth hormone and androgens within 4 weeks prior to the baseline visit
- Administration of IV immunoglobulin within 28 days prior to the baseline visit
- Treatment with any cell-depleting therapies
- Stem cell transplant at any time
- Participant who has received live or attenuated vaccines within 4 weeks prior to the baseline visit, or intending to receive while on study drug or 3 months following the last dose of study drug