ForPatients
by Roche

Juvenile Idiopathic Arthritis

A Study of Subcutaneously Administered Tocilizumab in Participants With Systemic Juvenile Idiopathic Arthritis

Trial Status	Trial Runs In	Trial Identifier
Completed	12 Countries	NCT01904292 2012-003490-26 WA28118

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 Ib, Open-Label, Multicenter Study to Investigate the Pharmacokinetics, Pharmacodynamics, and Safety of Tocilizumab Following Subcutaneous Administration to Patients With Systemic Juvenile Idiopathic Arthritis

Trial Summary:

This open-label, multicenter study will evaluate the pharmacokinetics, pharmacodynamics, and safety of subcutaneously administered tocilizumab in participants with Systemic Juvenile Idiopathic Arthritis (sJIA). Participants with body weight less than (<) 30 kilograms (kg) will receive subcutaneous (SC) tocilizumab dose every 2 weeks (Q2W) and participants with body weight greater than or equal to (>=) 30 kg will receive weekly (QW), for 52 weeks. Tocilizumab was administered every 10 days until pre-planned interim analysis was performed and changed to Q2W in participants with body weight <30 kg.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT01904292 2012-003490-26 WA28118
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#1 Year & # 17 Years	No

Inclusion Criteria:

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- Diagnosis of sJIA according to the International League of Associations for Rheumatology (ILAR) classification
- History of inadequate clinical response (in the opinion of the treating physician) to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and corticosteroids
- If a participant has received previous treatment with any biologic agents other than tocilizumab, these must have been discontinued according to the timelines defined by protocol prior to the baseline visit
- Participants currently receiving tocilizumab by the intravenous (IV) route of administration and with well-controlled disease do not require a period of discontinuation of IV tocilizumab and should have their first dose of SC tocilizumab administered on the date that their next IV tocilizumab infusion would be due
- Concurrent treatment with Disease Modifying Anti-Rheumatic Drugs (DMARDs) including methotrexate (MTX), NSAIDs, and oral corticosteroids are permitted at the discretion of the investigator
- Participants of reproductive potential must be willing to use highly effective contraceptive methods

Exclusion Criteria:

- Prior discontinuation of IV tocilizumab because of inadequate clinical response or safety events (including hypersensitivity)
- Participants with poorly controlled disease (in the opinion of the treating physician) despite current treatment with IV tocilizumab
- sJIA that is well controlled by any treatment agent other than tocilizumab (Juvenile Arthritis Disease Activity Score of 71 Joints [JADAS-71] less than or equal to [<=] 3.8 with no fever)
- Participants who are wheelchair-bound or bedridden
- Any other auto-immune, rheumatic disease, or overlapping syndrome other than sJIA
- Lack of recovery from recent surgery or an interval of <6 weeks since surgery at the time of the screening visit
- Females who are pregnant, lactating, or intending to become pregnant during study conduct
- Any significant concurrent medical or surgical condition that would jeopardize the participant's safety or ability to complete the study
- Known Human Immunodeficiency Virus (HIV) infection or other acquired forms of immune compromise or inborn conditions characterized by a compromised immune system
- History of alcohol, drug, or chemical abuse within 6 months of screening
- Any active acute, subacute, chronic, or recurrent bacterial, viral, or systemic fungal infection or any major episode of infection requiring hospitalization or treatment during screening or treatment with IV antibiotics completed within 4 weeks of the screening visit or oral antibiotics completed within 2 weeks of the screening visit
- History of atypical tuberculosis (TB) or active TB requiring treatment within 2 years prior to screening visit
- Positive TB test at screening unless treated with anti-TB therapy for at least 4 weeks prior to receiving study drug
- History of reactivation or new onset of a systemic infection such as herpes zoster or Epstein-Barr virus within 2 months of the screening visit
- Hepatitis B surface antigen or hepatitis C antibody positivity or chronic viral or autoimmune hepatitis
- History of concurrent serious gastrointestinal disorders such as ulcer or inflammatory bowel disease, Crohn's disease, ulcerative colitis, or other symptomatic lower gastrointestinal conditions
- History of or current cancer or lymphoma
- Uncontrolled diabetes mellitus with elevated glycosylated hemoglobin
- Macrophage activation syndrome (MAS) within 3 months of the screening visit
- Inadequate hematologic, renal or liver function

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