ForPatients
by Roche

Juvenile Idiopathic Arthritis

A Study of Subcutaneously (SC) Administered Tocilizumab (TCZ) in Participants With Polyarticular-Course Juvenile Idiopathic Arthritis (pJIA)

Trial Status	Trial Runs In	Trial Identifier
Completed	12 Countries	NCT01904279 2012-003486-18 WA28117

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 Polyarticular Juvenile Idiopathic Arthritis

Trial Summary:

This open-label, multicenter study evaluated the pharmacokinetics, pharmacodynamics and safety of SC administered TCZ in participants with pJIA.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT01904279 2012-003486-18 WA28117
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Ages 1 year (12 years for participants in Russia) up to and including 17 years at screening
- Diagnosis of pJIA according to International League of Associations for Rheumatology classification
- Rheumatoid factor (RF)-positive pJIA
- RF-negative pJIA
- Extended oligoarticular JIA with a polyarticular course

- History of inadequate clinical response (in the opinion of the treating physician) to or inability to tolerate methotrexate (MTX)
- Participants currently receiving TCZ by the intravenous (IV) route of administration and with well-controlled disease do not require a period of discontinuation of IV TCZ and should have their first dose of SC TCZ administered on the date that their next IV TCZ infusion would be due. Participants participating in the study may be either naive to TCZ therapy or may be switching from IV to SC. The total number of participants switching from IV TCZ must account for no more than 50 percent (%) of the total participant number. To account for the baseline TCZ concentrations in these participants, information on the last 4 IV TCZ infusions prior to baseline will be collected
- Concurrent treatment with disease-modifying antirheumatic drugs (DMARDs) (including MTX), nonsteroidal anti-inflammatory drugs (NSAIDs), and oral corticosteroids are permitted at the discretion of the investigator
- Females of childbearing potential and non-sterile males with female partner of childbearing potential must agree to use effective contraception as defined by protocol

Exclusion Criteria:

- Prior discontinuation of IV TCZ 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 TCZ
- pJIA that is well controlled by any treatment agent other than TCZ (Juvenile Arthritis Disease Activity Score 71 [JADAS-71] less than or equal to (< / =) 3.8)
- Participants who are wheelchair-bound or bedridden
- Any other auto-immune, rheumatic disease, or overlapping syndrome other than the permitted pcJIA subsets
- 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 purified protein derivative (PPD) at screen, unless treated with anti-TB therapy for at least 4 weeks prior to receiving study drug and chest radiograph is negative for active TB within 6 months of screening visit according to local practice
- 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
- Active uveitis at screening
- Inadequate hematologic, renal or liver function

- Prior stem cell transplant at any time