ForPatients
by Roche

Juvenile Idiopathic Arthritis

A Study of Decreased Dose Frequency in Participants With Systemic Juvenile Arthritis Who Experience Laboratory Abnormalities During Treatment With RoActemra/Actemra (Tocilizumab)

Trial Status	Trial Runs In	Trial Identifier
Completed	10 Countries	NCT01734382 2012-000444-10 WA28029

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 Study to Evaluate Decreased Dose Frequency in Patients With Systemic Juvenile Arthritis (SJIA) Who Experience Laboratory Abnormalities During Treatment With Tocilizumab

Trial Summary:

PART1 Participants in Part 1 (Run-in-Phase) of study will receive tocilizumab (TCZ) (RoActemra/Actemra) 12 milligrams per kilogram (mg/kg) or 8 mg/kg intravenously (IV) every 2 weeks (Q2W) for up to 24 weeks. Participants who experience a laboratory abnormality during Part 1 may be eligible to move into Part 2 of the study. PART 2 This open-label Phase IV study will evaluate the efficacy, safety, pharmacokinetics, pharmacodynamics and immunogenicity of tocilizumab in reduced dose frequency in participants with adequately controlled systemic juvenile idiopathic arthritis who have experienced a laboratory abnormality on twice weekly tocilizumab dosing, that has since resolved. Participants will receive tocilizumab 12 mg/kg or 8 mg/kg intravenously every 3 weeks. After 5 consecutive infusions, participants who experience an event of neutropenia, thrombocytopenia or liver enzyme abnormality will move to every 4 weeks tocilizumab administration. Anticipated time on study treatment is 52 weeks.

Hoffmann-La Roche	**Phase 4**
Sponsor	Phase

NCT01734382 2012-000444-10 WA28029
Trial Identifiers

Eligibility Criteria:

Gender	**Age**	**Healthy Volunteers**

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All	#2 Years & # 17 Years	No

Inclusion Criteria:

PART 1 and 2

- Children 2 to 17 years of age inclusive at screening
- Systemic juvenile idiopathic arthritis (sJIA) according to International League of Associations for Rheumatology (ILAR) classification (2001) and sJIA symptoms lasting for at least 1 month since diagnosis of sJIA
- Must meet one of the following:
- Not receiving methotrexate (MTX) or discontinued MTX at least 4 weeks prior to baseline visit, or
- Taking MTX for at least 12 weeks immediately prior to the baseline visit and on a stable dose of less than or equals (</=) 20 milligrams per meter square (mg/m^2) for at least 8 weeks prior to the baseline visit, together with either folic acid or folinic acid according to local standard of care
- Participants entering Part 1 who are naive to TCZ therapy must also meet the following inclusion criterion:
- History of inadequate clinical response (in the opinion of the treating physician) to Non steroidal Anti-Inflammatory Drugs (NSAIDs) and corticosteroids PART 2
- Juvenile Arthritis Disease Activity Score (JADAS) -71 score of 3.8 or less and absence of fever (related to sJIA) at screening and baseline
- Neutropenia, thrombocytopenia, or elevated Alanine transaminase/Aspartate transaminase (ALT/AST) previously experienced on the labeled dose (Q2W) of RoActemra/Actemra at any time
- Not currently receiving oral corticosteroids, or taking oral corticosteroids at a stable dose for a minimum of 2 weeks prior to baseline visit at no more than 10 milligrams per day (mg/day) or 0.2 miiligrams per kilogram per day (mg/kg/day), whichever is less
- Not taking (NSAIDs), or taking no more than 1 type of NSAID at a stable dose for a minimum of 2 weeks prior to the baseline visit, with the dose being less than or equal to the maximum recommended daily dose

Exclusion Criteria:

- Wheelchair bound or bedridden
- Any other auto-immune, rheumatic disease, or overlap syndrome other than sJIA
- Pregnant or lactating, or intending to become pregnant during study conduct and up to 6 months after the last administration of study drug
- Any significant concurrent medical or surgical condition which would jeopardize the participant's safety or ability to complete the trial
- History of significant allergic or infusion reactions to prior TCZ infusion, and/or presence of anti-TCZ antibodies at screening
- Inborn conditions characterized by a compromised immune system
- Known Human Immunodeficiency Virus (HIV) infection or other acquired forms of immune compromise
- History of alcohol, drug, or chemical abuse within 6 months of screening
- Evidence of serious uncontrolled concomitant diseases, including but not limited to the nervous, renal, hepatic, or endocrine systems
- Any active acute, subacute, chronic or recurrent bacterial, viral, or systemic fungal infection
- History of atypical tuberculosis (TB)
- Active TB requiring treatment within 2 years prior to the screening visit
- Positive purified protein derivative (PPD) at screening

- Any major episode of infection requiring hospitalization or treatment during screening or 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 reactivation or new onset of a systemic infection within 2 months of the screening visit
- Positive for hepatitis B or hepatitis C infection
- Chronic hepatitis, viral or pulmonary disease
- Significant cardiac or pulmonary disease
- History of or current cancer or lymphoma
- Uncontrolled diabetes mellitus
- History of or concurrent serious gastrointestinal disorders
- History of macrophage activation syndrome (MAS) within 3 months prior to screening visit