ForPatients
by Roche

Artritis Idiopática Juvenil

WA28029 Estudio de frecuencia de dosis disminuida en participantes con artritis juvenil sistémica que experimentan anomalías de laboratorio durante el tratamiento con RoActemra/Actemra (tocilizumab) (ARTHUR)

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
Finalizado	10 Countries	NCT01734382 2012-000444-10 WA28029

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

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 RoActemra/Actemra (tocilizumab) in reduced dose frequency in participants with adequately controlled systemic juvenile idiopathic arthritis who have experienced a laboratory abnormality on twice weekly RoActemra/Actemra dosing, that has since resolved. Participants will receive RoActemra/Actemra 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 RoActemra/Actemra administration. Anticipated time on study treatment is 52 weeks.

Hoffmann-La Roche	Phase 4
Sponsor	Phase

Eligibility Criteria:

Gender	Age	Healthy Volunteers
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