ForPatients
by Roche

Rheumatoid Arthritis

An Efficacy and Safety Study of Subcutaneous Tocilizumab in Combination With Methotrexate (MTX) and as Monotherapy Versus MTX in Participants With Moderate to Severe Rheumatoid Arthritis With Inadequate Response to Current Disease-Modifying Antirheumatic Drug (DMARD) Therapy

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03155347 YA29359

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 Randomized, Multi-Center, Double Blind, Parallel-Group Study to Evaluate the Efficacy and Safety of Subcutaneous (SC) Tocilizumab (TCZ) in Combination With Methotrexate (MTX) and as Monotherapy Versus MTX in Patients With Moderate to Severe Rheumatoid Arthritis With Inadequate Response to Current DMARD Therapy

Trial Summary:

This is a randomized, double-blind, multi-center, parallel-group study to evaluate the efficacy and safety of subcutaneous (SC) tocilizumab (162 milligrams [mg] every 2 weeks [Q2W]) given as monotherapy and in combination with MTX versus MTX given as monotherapy, in participants with moderate to severe active rheumatoid arthritis (RA) who have inadequate response to current DMARD therapy. The study comprises a 24-week double-blind treatment phase, followed by a 24-week extension phase.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT03155347 YA29359
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 70 Years	No

Inclusion Criteria:

- Chinese participants who are located in mainland China with RA of greater than or equal to (>=) 6 months' duration from onset of the disease, diagnosed according to the revised 1987 ACR criteria and receiving treatment on an outpatient basis
- Participants must have discontinued etanercept (or YiSaiPu) for >= 2 weeks, infliximab, certolizumab, golimumab, abatacept or adalimumab for >= 8 weeks, anakinra for >= 1 week prior to randomization
- Have received oral MTX at a stable dose for at least 12 weeks prior to baseline (MTX dose 10 to 25 mg) and experience of failing at least one non-biologic DMARD including MTX
- All treatment with non-biological DMARDs except MTX should be withdrawn at least 2 weeks prior to baseline (leflunomide for >= 12 weeks or >= 14 days after standard cholestyramine or activated charcoal washout, azathioprine for >= 4 weeks)
- SJC >= 6 (on the basis of 66 joint counts) and TJC >= 8 (on the basis of 68 joint counts) at screening and baseline with at least 3 months of treatment with permitted DMARDs
- Participants must have either high sensitive CRP >= 10 milligrams per liter (mg/L) or ESR >=28 millimeters per hour (mm/hr) at screening
- Oral corticosteroids (<=10 mg/day prednisone or equivalent) and nonsteroidal anti-inflammatory drug (NSAIDs; up to the maximum recommended dose per local standard of care) are permitted if the dose has been stable for at least 4 weeks prior to baseline
- All treatment with Chinese traditional medicine and/or herb medicine for RA treatment should be withdrawn at least 2 weeks prior to baseline
- Females of childbearing potential and males with female partners of childbearing potential may participate only if using a reliable means of contraception as defined by the protocol

Exclusion Criteria:

- Participants with major surgery or planned major surgery, rheumatic autoimmune disease other than RA, and functional class IV (as defined by the ACR Classification of Functional Status in RA)
- Participants with unsuccessful treatment with an anti-tumor necrosis factor (anti-TNF) agent; previous treatment with any cell-depleting therapies including investigational agents and janus kinase (JAK) inhibitors or any other new agents which have DMARD/DMARD-like effect; treatment with intravenous (IV) gamma-globulin, plasmapheresis, or Prosorba column; treatment with alkylating agents
- Intra-articular or parenteral corticosteroids and/or immunization with a live/attenuated vaccine within 4 weeks prior to baseline
- History of severe allergic or anaphylactic reactions to human, humanized, or murine monoclonal antibodies
- Primary or secondary immunodeficiency (history of or currently active)
- Evidence of serious uncontrolled concomitant diseases and disease states; evidence of active malignant disease
- Participants with abnormal haematological parameters, abnormal renal and hepatic parameters
- Positive for either hepatitis B surface antigen (HBsAg) or hepatitis B core antibody (HBcAb) and/or hepatitis C virus (HCV) antibody