ForPatients
by Roche

Rheumatoid Arthritis

A Study to Assess the Efficacy and Safety of RO7790121 in Participants With Moderate to Severe Rheumatoid Arthritis Who Have Not Responded to or Who Cannot Tolerate Tumor Necrosis Factor (TNF) and/or Janus Kinase (JAK Inhibitors)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07137598 WA45846

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 II, Multicenter, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of RO7790121 in Participants With Moderate to Severe Rheumatoid Arthritis Who Have an Inadequate Response or Intolerance to TNF and/or JAK Inhibitors

Trial Summary:

This study will assess the efficacy and safety of Afimkibart (also known as RO7790121) compared with placebo in participants with moderate to severe rheumatoid arthritis (RA) who have an inadequate response or intolerance to TNF and/or JAK inhibitors.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT07137598 WA45846
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Has moderate to severe active RA defined by the presence of >= 6 swollen joints and >= tender joints at screening and baseline (based on 66/68-joint count)

- Diagnosis of RA for >= 3 months and also fulfills the 2010 American College of Rheumatology (ACR)/ European Alliance of Associations for Rheumatology (EULAR) classification criteria for RA
- Demonstrated an inadequate response or loss of response to or intolerance to >= 1 conventional synthetic disease-modifying antirheumatic drug (csDMARD)

Exclusion Criteria:

- Have failed more than two TNF inhibitors or JAK inhibitors
- Class IV RA according to ACR revised response criteria (Hochberg et al. 1992)
- Past or current use of other biologic disease-modifying antirheumatic drugs (bDMARDs) (excluding TNF inhibitors) or rituximab
- Treatment with investigational therapy within 4 weeks or within 5 half-lives of the investigational therapy, whichever is longer, prior to initiation of study treatment.
- History of any arthritis with onset prior to age 17 years or current diagnosis of inflammatory joint disease other than RA
- Has been treated with intra-articular, intramuscular, intravenous, trigger point or tender point, intra-bursa, or intra-tendon sheath corticosteroids in the preceding 8 weeks prior to the first dose of study drug
- History of a severe allergic reaction or anaphylactic reaction or known hypersensitivity to any component of the study drug (or its excipients) and/or other products in the same class
- Any major surgery within 6 weeks prior to screening or a major surgery planned during the study
- Any serious, chronic and/or unstable pre-existing medical, psychiatric, or other- condition
- History of malignancy, with the exception non-metastatic basal cell or cutaneous squamous cell cancer adequately treated with electrodesiccation and curettage or resection or in situ cervical cancer adequately treated and cured
- Participants with severe chronic or recurrent viral, bacterial, parasitic, or fungal infections
- History of active hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV) infection
- History of organ transplant
- Any identified confirmed congenital or acquired immunodeficiency
- Abnormal laboratory values and liver function test