ForPatients
by Roche

Systemic Sclerosis

A Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of RO7303509 in Participants With Systemic Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	12 Countries	NCT05462522 2021-004578-68 GA43360

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, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Multiple-Ascending Doses of RO7303509 in Participants With Systemic Sclerosis

Trial Summary:

The purpose of this study is to evaluate the safety, tolerability, and pharmacokinetics (PK) of RO7303509 treatment in participants with systemic sclerosis (SSc) during a multiple-ascending-dose (MAD) portion of the trial. In the MAD phase, increasing doses of study drug will be tested sequentially. For each dose tested, the MAD stage will consist of a treatment period of 12 weeks followed by either a safety follow-up period of 13 weeks or continued treatment in an optional open-label safety extension (OSE) stage of 52 weeks to assess the long-term safety. All patients in the OSE stage will receive RO7303509 and no patient will receive placebo.

Genentech, Inc.	Phase 1
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

Inclusion Criteria:

Inclusion Criteria for the MAD Stage:

- Weight of 45-150 kg at screening
- Diagnosis of SSc, as defined by 2013 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) criteria and # 10 years disease duration from first non-Raynaud's symptom
- Agreement to remain abstinent or use an effective contraceptive method among males and females with childbearing potential for 4 months after last dose of study drug

Inclusion Criteria for the OSE Stage:

- No clinically significant change in eligibility status
- Completion of the MAD and ability to roll over into the OSE within 5 days

Exclusion Criteria:

- Active rheumatic autoimmune disease other than SSc requiring treatment with disease-modifying therapy
- Pulmonary disease with forced vital capacity (FVC) # 50% of predicted
- History or clinical manifestations of significant metabolic, hepatic, renal, pulmonary, cardiovascular, hematologic, gastrointestinal, urologic, neurologic, or psychiatric disorders
- History of severe allergic or anaphylactic reactions to human, humanized, or murine monoclonal antibodies
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 4 months after the final dose of study drug
- Major surgery within 8 weeks prior to screening, or major planned surgery during the study or within 3 months after the final dose
- Positive hepatitis C virus (HCV) antibody, hepatitis B surface antigen (HBsAg), or human immunodeficiency virus (HIV) antibody test at screening
- Any serious medical condition or abnormality in clinical laboratory tests