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A study to evaluate the safety of RO7303509 in healthy volunteers

Submission date 06/08/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/08/2020	**Overall study status** Completed	
Last Edited 26/04/2024	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
The aim of this study is to test RO7303509 compared with placebo at different doses, to find out if it is safe and to understand the way people process the drug. A placebo looks like a drug but has no active ingredient.

Who can participate?
Healthy male and female volunteers aged 18 to 75 years, inclusive

What does the study involve?
Participants are randomly assigned to receive either RO7303509 or placebo as a single dose to determine the safety of the drug. The total maximum study duration on study for participants is about 85 days.

What are the possible benefits and risks of participating?
Participants are not expected to receive any direct benefits from the study, but the information that is learned may help other people in the future. RO7303509 has not yet been tested in humans. For this reason, the side effects of this drug are not known at this time.

Where is the study run from?
Alliance for Multispecialty Research, LLC (USA)

When is the study starting and how long is it expected to run for?
May 2020 to May 2022

Who is funding the study?
Genentech, Inc. (USA)

Who is the main contact?
global-roche-genentech-trials@gene.com

Contact information

Type(s)
Scientific

Contact name
Dr Clinical Trials

Contact details
Genentech, Inc.
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GA42285

Study information

Scientific Title
A Phase Ia, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of single-ascending doses of RO7303509 in healthy volunteers

Study objectives
To assess the safety, tolerability and pharmacokinetics of single-ascending doses of R07303509 in healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/08/2020, Advarra IRB (6940 Columbia Gateway Drive, Suite 110, Columbia, MD 21046, USA; +1 4108842900; no email provided), ref: none provided

Study design
Phase Ia randomized double-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Inflammation

Interventions
Current intervention as of 22/07/2022:
Participants will be randomized to the treatment arms through an interactive voice or web-based response system (IxRS). In this single-ascending dose (SAD) study, each cohort will evaluate either IV or SC administration of RO7303509. The initial dose of RO7303509 will be 50 mg IV and single doses of 150 mg IV (Cohort B), 240 mg IV (Cohort C), and 240 mg SC Cohort D) have been tested. Cohort E will receive 675 mg SC and the highest dose will be determined based on the review of safety, PK, and anti-drug antibody (ADA) data (if available) and will not exceed 1200 mg SC. All participants will reside at the clinical research unit for a minimum of 48 hours after dosing. Participants will then return for regularly scheduled non-residential follow-up visits through Day 85.

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Previous intervention:
Participants will be randomized to the treatment arms through an interactive voice or web-based response system (IxRS). In this single-ascending dose (SAD) study, each cohort will evaluate either IV or SC administration of RO7303509. The initial dose of RO7303509 will be 50 mg IV and the highest dose will be determined based on review of safety and PK data. All participants will reside at the clinical research unit for a minimum of 48 hours after dosing. Participants will then return for regularly scheduled non-residential follow-up visits through Day 85.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
RO7303509

Primary outcome measure
The safety of single doses of RO7303509 according to the World Health Organization (WHO) Toxicity Grading Scale and vital signs, labs and ECG from baseline to day 85

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/05/2020

Completion date
19/05/2022

Eligibility

Key inclusion criteria
1. Age ≥18 years and ≤75 years
2. Ability to comply with the study protocol, in the investigator’s judgment
3. Use of contraceptive measures

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
57

Total final enrolment
57

Key exclusion criteria
1. Pregnant or breastfeeding, or intending to become pregnant during the study or within 85 days after the dose of RO7303509
2. No comorbid conditions that may interfere with the evaluation of an investigational medical product
3. No history or evidence of substance abuse that would pose a risk to participants safety, interfere with the conduct of the study, or have an impact on the study results
4. History of severe allergic or anaphylactic reactions to human, humanized, or Current treatment with medications that are well known to prolong the QT

Date of first enrolment
29/09/2020

Date of final enrolment
24/02/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Alliance for Multispecialty Research LLC
Knoxville
United States of America
37920

Sponsor information

Organisation
Genentech, Inc.

Sponsor details
1 DNA Way
South San Francisco
United States of America
94080
+1 (0)888 662 6728
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Sponsor type
Industry

Website
http://www.roche.com/about_roche/roche_worldwide.htm

Funder(s)

Funder type
Industry

Funder Name
Genentech

Alternative Name(s)

Genentech, Inc., Genentech USA, Inc., Genentech USA

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal approximately 1 year after the anticipated trial end date. Additional trial documents (i.e., study protocol) will not be made available.

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
Data will not be shared to protect the privacy of trial participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/04/2024	26/04/2024	Yes	No