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A study to evaluate the safety, tolerability, processing by the body, and response of the body to the drug RO7497987 in single and multiple ascending doses in healthy volunteers

Submission date 24/11/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/11/2021	**Overall study status** Completed	
Last Edited 07/02/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The aim of this study is to test the drug RO7497987 at different doses to find out if it is safe, to find out the effects of RO7497987 on the body, and to understand how the human body processes it. In this study, participants will receive either one or two dose(s) of RO7497987. RO7497987 is an experimental drug, which means health authorities have not approved RO7497987 for the treatment of any disease, and it has not been tested in people before this study.

Who can participate?
Healthy people aged between 18 to 65 years old.

What does the study involve?
Participants will be screened to see if they may participate in the study. During screening, participants undergo a physical examination and electrocardiogram (ECG) and blood and urine samples will be taken. In addition, their height, weight, and vital signs will be measured.
Participants will be placed in one of the following treatment groups. Group 1 will receive one dose of RO7497987 given as an infusion (into the vein). Group 2 will receive multiple doses of RO7497987, given as an infusion.
Treatment will be given in a clinic. Participants will be required to check into the treatment center 1 day before they receive the study treatment, and the duration of time participants will stay in the treatment center is based on the treatment assigned.
After the treatment period ends, participants will return to the clinic for follow-up visits. During these visits, participants will be asked about their well-being, their vital signs will be taken and additional blood samples will be collected.

What are the possible benefits and risks of participating?
Participants will not receive any benefit from participating in this study, but the information that is learned may help people with certain cancers in the future.

The potential side effects related to the study drug, based on laboratory studies or knowledge of similar drugs, are listed below:
1. Infusion-related or allergic reaction with symptoms such as fever, chills, etc
2. Minimal to mild increase in liver enzymes
3. Increase in the size of participant's lymph nodes, spleen, or other organs
4. Interactions with vaccine/immunisation
5. There may be a risk in exposing an unborn child to the study drug, and all the risks are not known at this time.

Where is the study run from?
F. Hoffmann-La Roche (USA)

When is the study starting and how long is it expected to run for?
June 2021 to January 2023

Who is funding the study?
F. Hoffmann-La Roche (USA)

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

Contact information

Type(s)
Public

Contact name
Dr Clinical Trials

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
GO43310

Study information

Scientific Title
A Phase IA, open-label study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of RO7497987 in single and multiple ascending doses in healthy volunteers

Study objectives
RO7497987 will be safe and well-tolerated in healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2021, WCG IRB (1019 39th Avenue SE, Suite 120, Puyallup, WA, 98374, USA; +1 (0)855 818 2289; researchquestions@wcgirb.com [given to subjects], clientservices@wcgirb.com [for CROs to contact the IRB]), ref: 20215288

Study design
Phase IA open-label single-centre dose-escalation study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Safety, tolerability, pharmacokinetics, and pharmacodynamics of RO7497987

Interventions
Single Ascending Dose (SAD): RO7497987 monotherapy single dose given intravenously (IV) at Cycle 1 Day 1. Cohorts of at least 6 participants each will be treated at escalating doses of RO7497987

Multiple Ascending Dose (MAD): RO7497987 monotherapy given intravenously (IV) at Cycle 1 Day 1 and Cycle 2 Day 1, 21 days apart. Cohorts of at least 6 participants each will be treated with RO7497987 at dose levels determined based on the safety data, tolerability, pharmacokinetics, and pharmacodynamics tested in the SAD cohorts

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
RO7497987

Primary outcome(s)
1. Percentage of participants with adverse events and severity per National Cancer Institute-Common Terminology Criteria for Adverse Events Version 5.0 (NCI-CTCAE V5.0) from screening up to approximately 13 months
2. Targeted vital signs measured using clinical examinations at every visit from study initiation up to approximately 3 months after the last dose
3. Targeted clinical laboratory test results measured using blood and urine samples at selected timepoints from study initiation up to approximately 3 months after the last dose

Key secondary outcome(s))
1. Myeloid cells in the peripheral blood following administration of RO7497987 measured using blood samples at multiple timepoints from study initiation up to approximately 3 months after the last dose
2. Serum concentration of RO7497987 measured using blood samples at multiple timepoints from study initiation up to approximately 3 months after the last dose
3. Pharmacokinetic parameters (i.e., AUC, Tmax, Cmax, CL, Vss/F, and t1/2) measured using blood samples at multiple timepoints from study initiation up to approximately 3 months after the last dose
4. Prevalence and incidence of anti-drug antibodies measured using blood samples at baseline and after initiation of study treatment, from study initiation up to approximately 13 months

Completion date
19/01/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years and ≤65 years at the time of signing Informed Consent Form (ICF)
2. A minimum weight of 40 kg at screening
3. Body mass index of 18-32 kg/m² at screening
4. Adequate hematologic and end-organ function

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. History or active diseases of bone marrow disorders
2. History of malignancy within 5 years prior to screening
3. Vaccine immunization within 2 weeks prior to initiation of study drug
4. Known infection/COVID-19 positive or persistent symptoms of SARS-CoV-2
5. HIV positive
6. Active Hepatitis B or Hepatitis C infections
7. Current tobacco use
8. History or currently active of autoimmune disease

9. Significant cardiovascular disease
10. Known clinically significant liver and renal diseases

Date of first enrolment
30/11/2021

Date of final enrolment
28/08/2022

Locations

Countries of recruitment
United States of America

Study participating centre
PRA Lenexa Clinic
Lenexa
United States of America
66219

Sponsor information

Organisation
Roche (United States)

ROR
https://ror.org/011qkaj49

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement

IPD sharing plan summary
Not expected to be made available