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A study to investigate the safety, tolerability, and processing by the body of RO7223280 following single-dose administration in healthy Chinese participants

Submission date 02/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/02/2023	**Overall study status** Completed	
Last Edited 03/02/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The study drug RO7223280 is being developed for the possible treatment of bacterial infection caused by the bacteria Acinetobacter baumannii. RO7223280 is an experimental drug, which means Health Authorities have not approved RO7223280 for treating any bacterial infection. This study aims to test the safety of RO7223280 at different dose levels and to find out the effects, good or bad, of RO7223280 on the study participants.

Who can participate?
Healthy Chinese males and females aged between 18 and 64 years old

What does the study involve?
Participants will have to be a part of the study for about 6weeks (from screening to follow-up), which will be divided as follows:
Screening Period: To check if the participants are eligible for the study. This visit will occur up to 28 days before the study treatment administration.
Treatment Period (residential/in-house): The participant will need to come to the clinic 1 day before the treatment administration (Day –1) and stay in the clinic for 5 nights (from Day -1 to Day 5).

Participants will be randomly assigned to one of the treatment groups to receive one single IV dose of either 600 milligrams (mg), 1000 mg, or 1500 mg of RO7223280 or a placebo (a substance that looks like the study drug but contains no active medication) through a tube or cannula introduced into a vein in the arm (intravenous infusion) on Day 1 of the treatment period.

Follow-up: To check on the participant after treatment is finished. This visit will occur approximately 14days after the last study treatment administration.

What are the possible benefits and risks of participating?
RO7223280 is being given purely for research purposes, it is not intended for participants to receive any benefit from it. Future patients may benefit from the information collected in this study.

Participants may experience side effects from the study treatment or procedure. The side effects can vary from mild to very serious and may be different from person to person. RO7223280 has had limited testing in humans and not all side effects are known at this time.

The most common side effect includes infusion-related reactions (e.g., itching, flushing, shortness of breath). Other side effects include headache and side effects that are associated with either patch from the device that is used to monitor the heart electrocardiogram (ECG) or from the needle used to inject the drug (e.g., skin swelling (inflammation), skin bruising).

There may be a risk in exposing an unborn child to the study treatment, and not all potential consequences are known at this time. Women and men must take precautions to avoid exposing an unborn child or a breastfed baby to the study treatment. Participants who are pregnant, become pregnant, or are currently breastfeeding cannot take part in this study.

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

When is the study starting and how long is it expected to run for?
May 2022 to May 2023

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

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

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number

BP44069

Study information

Scientific Title
A sponsor-open, randomized, placebo-controlled, phase I study to investigate the pharmacokinetics, safety, and tolerability of RO7223280 in healthy Chinese participants following single IV dose administration

Study objectives
The purpose of this study is to evaluate the pharmacokinetics (PK), safety, and tolerability of RO7223280, a novel narrow-spectrum antibiotic, administered intravenously (IV) to healthy Chinese participants to support further global clinical development of RO7223280.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/11/2022, Ethics Review Committee of Huashan Hospital affiliated to Fudan University (No. 12, Urumqi Middle Road, Shanghai, 200040, China; 021-52888045; wucuiyun@fudan.edu.cn), ref: 2022M-017

Primary study design
Interventional

Study design
Phase I single-dose sponsor-open randomized placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
RO7223280: Participants in each cohort will receive a single dose of RO7223280 or a matching placebo, as an IV infusion, on Day 1 of the dosing period. The planned dose-escalation sequence is 600 milligrams (mg), 1000 mg and 1500mg.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
RO7223280

Primary outcome(s)

1. Time to maximum plasma concentration (Tmax) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
2. Maximum observed serum concentration (Cmax) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
3. Time to the last measurable time point (Tlast) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
4. Observed last measurable plasma concentration (Clast) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
5. Area under the plasma concentration versus time curve from zero to the last measurable concentration (AUClast) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
6. Area under the plasma concentration versus time curve from zero to 72 hours (AUC0-72) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
7. Area under the plasma concentration versus time curve extrapolated to Infinity (AUCinf) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
8. Terminal rate constant (λz) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
9. Apparent terminal half-life (T1/2) of RO7223280 Calculated Using Standard Non-compartmental Methods of Analysis at Pre-dose and Multiple Time-points Post-dose from Day 1 up to Day 5
10. Total body clearance (CL) of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
11. Volume of distribution at steady-state (V of RO7223280 calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 5
12. Amount of RO7223280 excreted (Ae) into urine calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 4
13. Fraction of the dose of RO7223280 administered excreted (Fe) into urine calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 4
14. Renal clearance (CLr) of RO7223280, calculated using standard non-compartmental methods of analysis at pre-dose and multiple time-points post-dose from Day 1 up to Day 4
15. Number of participants with adverse events (AEs) and severity of AEs determined according to National Cancer Institute common terminology criteria for adverse events version 5.0 (NCI CTCAE v5.0) from screening up to 14 days after the last study treatment administration (up to approximately 44 days)

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
19/05/2023

Eligibility

Key inclusion criteria
1. Participants aged 18 to 64 years inclusive at screening
2. Healthy Chinese males and females (women of non-childbearing potential [WONCBP]) participants
3. Body weight of at least 50 kilograms (kg) and body mass index (BMI) within the range of 18 to 32 kilograms per square meter (kg/m2) (inclusive)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. History or evidence of any medical condition potentially altering the absorption, metabolism, or elimination of drugs
2. History of malignancy
3. Vaccination is prohibited within two months prior to Day 1
4. Use of glucocorticoids and other immunosuppressive medications is prohibited within 30 days (or within five times the elimination half-life, whichever is longer), prior to Day 1
5. Participation in an investigational drug medicinal product or medical device study within 30 days prior to screening or within five times the elimination half-life if known, whichever is longer
6. Clinically significant abnormalities (as judged by the Investigator) in laboratory test results
7. Positive results on human immunodeficiency virus (HIV)-1, HIV-2, hepatitis B virus, or hepatitis C virus (HCV) tests (including hepatitis B surface antigen, HCV antibody, and HIV antigen /antibody tests at screening)

Date of first enrolment
24/02/2023

Date of final enrolment
28/04/2023

Locations

Countries of recruitment
China

Study participating centre
Huashan Hospital Affiliated to Fudan University
China
200040

Sponsor information

Organisation
F Hoffmann-La Roche Ltd

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 analyzed 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