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A study to evaluate the safety and the processing of GDC-0829 by the body in healthy participants

Submission date	**Recruitment status**	[X] Prospectively registered
16/01/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/01/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/09/2025	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The study drug GDC-0829 is an experimental drug being developed to treat infections. GDC-0829 being an experimental drug means that the health authorities have not approved it for the treatment of infections or any other disease. This is the first study where this drug will be tested in humans. The main aim of this study is to test GDC-0829 at different doses to find out if it is safe and to understand how the body processes the drug.

Who can participate?
Healthy volunteers between 18 and 65 years of age

What does the study involve?
This study will be conducted in two stages: the Single Ascending Dose (SAD) stage followed by the Multiple Ascending Dose (MAD) stage. Participants in the SAD stage will need to be a part of this study for 15 days and participants in MAD will need to be a part of this study for 38 days (excluding the screening period of 28 days). Both SAD and MAD stages will have three parts:
1. Screening Period: Tests would be done to determine if the participant is eligible to take part in this study. The screening period is 28 days.
2. Treatment Period:
SAD Stage: During this period participants will receive either GDC-0829 or a placebo, which looks like a drug but has no active ingredients. Participants will be assigned to GDC-0829 or placebo by chance (like tossing a coin). Participants will receive a single dose of GDC-0829 or placebo infusion into the vein (intravenous [IV] infusion). Participants will be required to check in to the clinic 2 days before receiving the study drug and will have to stay at the clinic for about 5 nights.
MAD Stage: Participants will receive a dose of GDC-0829 or placebo multiple times per day. Participants will be required to check in to the clinic 2 days before receiving the study drug and have to stay at the clinic for about 18 nights.
3. Follow-up Visits: After participants complete the treatment, they will have to return to the clinic for follow-up visits. Participants in the SAD stage will have two follow-up visits with the

last visit taking place about 14 days after the dose of the study drug. Participants in the MAD stage will have four follow-up visits with the last visit taking place about 27 days after the last dose of the study drug.

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 infections in the future.
Participants may have side effects from GDC-0829 or procedures used in this study. These can be mild to severe and even life-threatening, and they can vary from person to person. GDC-0829 has not yet been tested in humans and thus side effects are not known at this time. The potential side effects are listed below:
1. Allergic reactions due to administration of the drug, which can be in the form of fever, chills, itching, difficulty breathing, a rash, and/or a drop in blood pressure.
2. There may be a decrease in kidney function.
3. There may be temporary loss of muscle coordination including awkward, uncoordinated walking or unsteadiness when walking.
4. There may be a reaction at the site where the drug was injected into the vein.
5. There may be damage to the liver.

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?
October 2023 to August 2025

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

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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Clinical Trials

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Additional identifiers

Protocol serial number

GV44796

Study information

Scientific Title
A Phase I, randomized, double-blind, single ascending dose and multiple ascending dose study to evaluate the safety and pharmacokinetics of GDC-0829 in healthy subjects

Study objectives
The main purpose of this study is to evaluate the safety and pharmacokinetics (PK) of single and multiple doses of GDC-0829 in healthy volunteers.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/12/2023, Advarra IRB (6100 Merriweather Drive, Suite 600, Columbia, 21044, United States of America; +1 (0)866 992 4724; cirbi@advarra.com), ref: Pro00076367

Primary study design
Interventional

Study design
Phase I single-centre interventional double-blinded randomized placebo-controlled dose-escalation study

Study type(s)
Treatment, Safety

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

Interventions
Participants will be randomized according to a master randomization list generated by the study Biostatistician in the KLD system. Participants will be randomly assigned to GDC-0829 or placebo in a 3:1 ratio within each cohort. Site personnel, aside from the unblinded pharmacy team, as well as participants, will be blinded to treatment assignment.

Single Ascending Dose (SAD) Cohorts: Participants will receive a single dose of GDC-0829 or placebo, as an intravenous (IV) infusion on Day 1 of the SAD stage. The doses of GDC-0829 in each cohort in the SAD stage will be determined per the decision made by the Safety Monitoring Committee (SMC) in consultation with the investigator.

Multiple Ascending Dose (MAD) Cohorts: Participants will receive GDC-0829 or placebo, as an IV infusion, multiple times a day for 11 days at escalating doses. The doses of GDC-0829 in each cohort in the MAD stage will be determined as per the decision made by the SMC in consultation with the investigator.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
GDC-0829

Primary outcome(s)
1. SAD: Number of participants with adverse events (AEs), with severity of AEs determined according to the Division of AIDS (DAIDS) toxicity grading scale, corrected version 2.1, July 2017 for most AEs and according to modified Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 grading scale from Screening up to 14 days after the final dose of study drug (up to approximately 15 days)
2. MAD: Number of participants with AEs, with severity of AEs determined according to the DAIDS toxicity grading scale, corrected version 2.1, July 2017 for most AEs and according to modified CTCAE version 5.0 grading scale from screening up to 28 days after the final dose of study drug (up to approximately 38 days)

Key secondary outcome(s)
1. SAD: Plasma concentration of GDC-0829 measured using blood samples collected at pre-dose and multiple timepoints post-dose from Day 1 to Day 15
2. SAD: Urine concentration of GDC-0829 measured using urine samples collected at pre-dose and multiple timepoints post-dose from Day -1 to Day 3
3. MAD: Plasma concentration of GDC-0829 measured using blood samples collected at pre-dose and multiple timepoints post-dose from Day 1 to Day 38
4. MAD: Urine concentration of GDC-0829 measured using urine samples collected at multiple timepoints post-dose on Day 11

Completion date
28/08/2025

Eligibility

Key inclusion criteria
1. Age 18 - 65 years at the time of signing the Informed Consent Form
2. Body mass index (BMI) ≥18.5 and <30 kilograms per metre squared (kg/m^2)
3. Ability to comply with the study protocol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit

65 Years

Sex
All

Total final enrolment
88

Key exclusion criteria
1. Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 28 days after the final dose of study drug
2. Planned procedure or surgery during the study
3. Positive human immunodeficiency virus (HIV) test at screening
4. Positive hepatitis B surface antigen (HBsAg) test at screening
5. Positive hepatitis C virus (HCV) antibody test at screening
6. Any serious medical condition or abnormality in clinical laboratory tests
7. History of malignancy within 5 years prior to screening
8. Acute illness within 14 days prior to screening
9. Vaccination within 14 days prior to initiation of study drug

Date of first enrolment
12/04/2024

Date of final enrolment
04/06/2025

Locations

Countries of recruitment
United States of America

Study participating centre
ICON, plc
9755 Ridge Drive
Lenexa, Kansas
United States of America
66219

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 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