

# A study to evaluate how inavolisib is processed in the body of participants with moderate and highly reduced kidney function

<b>Submission date</b> 15/11/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 05/12/2023	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study is testing a drug called inavolisib (also known as GDC-0077/RO7113755), which is being developed to treat certain kinds of cancer. Inavolisib is an experimental drug, which means health authorities have not approved inavolisib for the treatment of cancer or any other disease. The purpose of this study is to find out how much inavolisib gets into the body, and how long it takes the body to get rid of it (this is called pharmacokinetics [PK]) when given to participants with normal kidney function compared to participants with impaired kidney function. The other purpose of this study is to evaluate the safety and tolerability of inavolisib.

### Who can participate?

People who are 18 to 80 years of age (inclusive), with normal kidney function or moderate and severe kidney damage can participate in this study.

### What does the study involve?

Participants will be part of this study for approximately 6 weeks including screening and follow-up. The study will be conducted in the following parts:

1. Screening: During the screening period, participants will undergo certain screening tests and/or procedures to check if they are eligible to take part in this study. Participants will have one clinic visit and the screening period will be for approximately 32 days.
2. Dosing/Clinic Stay: Participants will receive a single dose of inavolisib by mouth during this period. They will be admitted to the clinic one day (Day -1) before inavolisib is administered and they will have to stay in the clinic for 5 days. Participants will have routine check-ups and blood samples will be collected during the clinic stay. They will be discharged on Day 5.
3. Follow-up Period: There will be a safety follow-up phone call 7 days after the study drug administration to check the participants' well-being after the treatment is finished.

### What are the possible benefits and risks of participating?

Participants will be administered inavolisib only for research purposes and it is not intended that the participants will receive any benefit from it. However, the information learned in this study

may help future patients suffering from certain kinds of cancers.

Participants may have side effects from inavolisib, or from procedures used in this study. These can be mild to severe and even life-threatening, and they can vary from person to person. Inavolisib has had limited testing in humans and there may be side effects that are not known at this time. The known and potential side effects associated with inavolisib are listed below:

**Known side effects:** Increased blood sugar levels (hyperglycemia), diarrhea, vomiting, nausea, constipation, rash, inflammation of the lining of the mouth or ulcers of the lip or mouth (mucosal inflammation/stomatitis).

**Potential side effects:** Eye disorder (eye pain or sensitivity to light, blurred vision, cataract); inflammation of the large bowel [colon] (colitis); possible harm to a developing unborn baby including birth defects and/or miscarriage; inflammation of the lungs that may cause difficulty breathing and can be life-threatening (pneumonitis); low levels of white blood cells that may lead to increased risk of infections (depressed immune function); low levels of cells that help the blood to clot (platelets), which may cause bleeding problems and bruising; in males, reduced fertility or sterility.

There may be a risk in exposing an unborn child to the study drug, and not all potential risks 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, or 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?

July 2023 to October 2024

Who is funding the study?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?

global.trial\_information@roche.com

### **Study website**

<https://forpatients.roche.com/en/trials/healthy-volunteers/a-phase-1--open-label--single-dose-study-to-evaluate-the-effect-.html>

## **Contact information**

### **Type(s)**

Public, Scientific, Principal Investigator

### **Contact name**

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### **Contact details**

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## Additional identifiers

### EudraCT/CTIS number

Nil Known

### IRAS number

### ClinicalTrials.gov number

Nil Known

### Secondary identifying numbers

GP44944

## Study information

### Scientific Title

A Phase 1, open-label, single-dose study to evaluate the effect of moderate or severe renal impairment on the pharmacokinetics of inavolisib

### Study objectives

The main purpose of this study is to evaluate the effect of moderate or severe renal impairment on the pharmacokinetics (PK) of inavolisib compared with demographically matched participants with normal renal function, following a single oral dose of inavolisib.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 14/08/2023, Salus IRB (2111 W. Braker Lane, Suite 100, Texas, Austin, 78758, United States of America; +1 512-380-1244; salus@salusirb.com), ref: None provided

### Study design

Phase 1 open-label multi-center single-dose non-randomized parallel-group study

### Primary study design

Interventional

### Secondary study design

Non randomised study

### Study setting(s)

Hospital

### Study type(s)

Treatment

## Participant information sheet

No participant information sheet available

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

Healthy Volunteers; Renal impairment

## Interventions

Participants with normal renal function, and moderate and severe renal impairment will receive a single dose of inavolisib, 6 milligrams (mg), orally on Day 1.

## Intervention Type

Drug

## Pharmaceutical study type(s)

Pharmacokinetic

## Phase

Phase I

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

Inavolisib

## Primary outcome measure

1. Area under the concentration-time curve (AUC) from hour 0 to the last measurable concentration (AUC<sub>0-t</sub>) of inavolisib, assessed using model-independent approach from the plasma samples collected at multiple time points from Day 1 to Day 5
2. AUC extrapolated to infinity (AUC<sub>0-∞</sub>) of inavolisib, assessed using model-independent approach from the plasma samples collected at multiple time points from Day 1 to Day 5
3. Maximum observed concentration (C<sub>max</sub>) of inavolisib, assessed using model-independent approach from the plasma samples collected at multiple time points from Day 1 to Day 5

## Secondary outcome measures

1. Number of participants with adverse events (AEs), and severity of AEs assessed according to National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0 (NCI CTCAE v5.0) from screening up to follow-up (approximately 6 weeks)

## Overall study start date

24/07/2023

## Completion date

22/10/2024

# Eligibility

## Key inclusion criteria

1. Participants must have a body weight of at least 45 kilograms (kg), and a body mass index (BMI) within the range of 18 - 40 kilograms per square meter (kg/m<sup>2</sup>) (inclusive).
2. Negative hepatitis panel (hepatitis B virus core antibody, hepatitis B surface antigen, and hepatitis C virus antibody) and negative human immunodeficiency virus (HIV) antibody screens.

Additional inclusion criteria for participants with normal renal function:

1. Participants must be in reasonably good health for their age group.
2. Estimated glomerular filtration rate (eGFR) of 90 millilitres per minute (mL/min), as calculated using 2021 Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) creatinine equation at screening and confirmed at Day -1.
3. Matched to participants with renal impairment in sex, age ( $\pm 10$  years), and body weight ( $\pm 15\%$ ).

Additional inclusion criteria for participants with moderate renal impairment:

1. Participants with moderate renal impairment must have eGFR 30-59 mL/min
2. Participants must have a stable renal function, defined as either:
  - 2.1. If the time interval between Screening and Check-in (Day -1) is greater than 7 days, eGFR value on Day -1 is within 20% of eGFR value at Screening, or
  - 2.2. If the time interval between Screening and Check-in (Day -1) is within 7 days, eGFR value on Day -1 is within 20% of eGFR value at Screening and there is no clinically significant change in eGFR over the past 3 months.
3. Stable medication regimen for at least 1 month prior to Check-in (Day -1)

Additional inclusion criteria for participants with severe renal impairment:

1. Participants with severe renal impairment must have eGFR  $< 30$  mL/min and not be on dialysis
2. Participants must have a stable renal function, defined as either:
  - 2.1. If the time interval between Screening and Check-in (Day -1) is greater than 7 days, eGFR value on Day -1 is within 20% of eGFR value at Screening, or
  - 2.2. If the time interval between Screening and Check-in (Day -1) is within 7 days, eGFR value on Day -1 is within 20% of eGFR value at Screening and there is no clinically significant change in eGFR over the past 3 months.
3. Stable medication regimen for at least 1 month prior to Check-in (Day -1).

### **Participant type(s)**

Healthy volunteer, Patient

### **Age group**

Mixed

### **Lower age limit**

18 Years

### **Upper age limit**

80 Years

### **Sex**

Both

### **Target number of participants**

32

### **Key exclusion criteria**

1. History of Type 1 diabetes or Type 2 diabetes requiring ongoing systemic treatment with 2 or more agents
2. Significant history or clinical manifestation of any metabolic, allergic, dermatological, hepatic, hematological, pulmonary, cardiovascular, gastrointestinal (GI), neurological, or psychiatric

disorder

3. Clinically significant and active liver disease, e.g., hepatitis, cirrhosis, or confirmed liver enzyme elevations.

4. History of stomach or intestinal surgery or resection that would potentially alter absorption and/or excretion of orally administered drugs except that appendectomy and hernia repair will be allowed.

5. Malabsorption syndrome or other condition that would interfere with enteral absorption. This includes gastric bypass surgery; gastric band surgery is allowed.

6. History of active or latent tuberculosis (TB), regardless of treatment history, or positive QuantiFERON® TB Gold test.

Additional exclusion criteria for participants with normal renal function:

1. Significant history or clinical manifestation of renal injury or disease (as determined by the investigator).

2. Uncomplicated cholecystectomy more than 5 years prior to enrolment is allowed unless the participant was  $\geq 40$  years old at the time of procedure; any cholecystectomy within 5 years of enrolment is exclusionary.

Additional exclusion criteria for participants with moderate and severe renal impairment:

1. Participants who have a functioning renal transplant or who are active on the transplant waiting list.

2. Blood potassium concentration  $<3$  millimoles per litre (mmol/L) or  $>6$  mmol/L at Screening

3. Hemoglobin concentration  $<9$  grams per deciliter (g/dL) at Screening.

**Date of first enrolment**

26/10/2023

**Date of final enrolment**

22/10/2024

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**

**Clinical Pharmacology of Miami, LLC**

550 West 84th St Miami

Miami, Florida

United States of America

33014-3616

**Study participating centre**

**Advanced Pharma CR, LLC**

2950 NW 83rd St. Miami

Miami, Florida  
United States of America  
33147

**Study participating centre**  
**Alliance for Multispecialty Research, LLC (AMR)**  
1928 Alcoa Highway, Suite 107, Knoxville,  
Knoxville, Tennessee  
United States of America  
37920

**Study participating centre**  
**Omega Research Orlando, LLC**  
816 Mercy Drive  
Orlando, Florida  
United States of America  
32808

**Study participating centre**  
**Orlando Clinical Research Center (OCRC-FL)**  
5055 S Orange Ave  
Orlando, Florida  
United States of America  
32809

**Study participating centre**  
**Pinnacle Research Group**  
409 E 10th St Suite 200  
Anniston, Alabama  
United States of America  
36207

## **Sponsor information**

**Organisation**  
F. Hoffmann-La Roche Ltd

**Sponsor details**

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Basel  
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CH-4070  
+41 616878333  
global.trial\_information@roche.com

**Sponsor type**

Industry

**Website**

<https://www.roche.com/about>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

F. Hoffmann-La Roche Ltd

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

22/10/2025

**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