

Renal FailureHealthy Volunteers

## A Phase 1, Open-label, Single-dose Study to Evaluate the Effect of Moderate or Severe Renal Impairment on the Pharmacokinetics of Inavolisib

**Trial Status**  
Completed

**Trial Runs In**  
1 Country

**Trial Identifier**  
GP44944 ISRCTN11899726

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

### *Official Title:*

A Phase 1, Open-label, Single-dose Study to Evaluate the Effect of Moderate or Severe Renal Impairment on the Pharmacokinetics of Inavolisib

### *Trial Summary:*

A Study to Evaluate how Inavolisib is Processed in the Body of Participants with Moderate and Highly Reduced Kidney Function

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

**Phase I**  
Phase

**GP44944 ISRCTN11899726**  
Trial Identifiers

### *Eligibility Criteria:*

**Gender**  
Both

**Age**  
18 to 80 years (inclusive)

**Healthy Volunteers**  
Yes

### **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.

# ForPatients

*by Roche*

The purpose of this study is to find out how much inavolisib gets into the body, 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:

- **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.
- **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.
- **Follow-up Period:** There will be a safety follow-up phone call 7 days after 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).

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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.

## **Who is funding the study?**

F. Hoffmann-La Roche Ltd

## **Who is the main contact?**

[global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)

## ***Inclusion Criteria:***

- 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).
- 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:**

- Participants must be in reasonably good health for their age group.
- 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.
- 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:**

- Participants with moderate renal impairment must have eGFR 30-59 mL/min
- Participants must have a stable renal function, defined as either:
  - 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
  - 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.
- Stable medication regimen for at least 1 month prior to Check-in (Day -1)

### **Additional inclusion criteria for participants with severe renal impairment:**

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- Participants with severe renal impairment must have eGFR <30 mL/min and not be on dialysis
- Participants must have a stable renal function, defined as either:
  - 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
  - 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.
- Stable medication regimen for at least 1 month prior to Check-in (Day -1).

## ***Exclusion Criteria:***

- History of Type 1 diabetes or Type 2 diabetes requiring ongoing systemic treatment with 2 or more agents
- Significant history or clinical manifestation of any metabolic, allergic, dermatological, hepatic, hematological, pulmonary, cardiovascular, gastrointestinal (GI), neurological, or psychiatric disorder
- Clinically significant and active liver disease, e.g., hepatitis, cirrhosis, or confirmed liver enzyme elevations.
- 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.
- Malabsorption syndrome or other condition that would interfere with enteral absorption. This includes gastric bypass surgery; gastric band surgery is allowed.
- 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:

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

- Participants who have a functioning renal transplant or who are active on the transplant waiting list.
- Blood potassium concentration <3 millimoles per litre (mmol/L) or >6 mmol/L at Screening
- Hemoglobin concentration <9 grams per deciliter (g/dL) at Screening.