

Renal Failure Healthy 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**  
Recruiting

**Trial Runs In**  
1 Countries

**Trial Identifier**  
GP44944

*The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.*

### ***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**  
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.

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?**

# ForPatients

*by Roche*

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).

**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.

# ForPatients

*by Roche*

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?**

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