ForPatients
*by Roche*

Liver Failure

# A Study to Evaluate the Effect of Moderate or Severe Hepatic Impairment on the Pharmacokinetics (PK) of Inavolisib

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Not yet recruiting | | NCT07144111 GP45942 |

*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 Hepatic Impairment on the Pharmacokinetics of Inavolisib

## *Trial Summary:*

This open-label study will evaluate the effect on the pharmacokinetics (PK), safety, and tolerability of a single oral dose of inavolisib in participants with moderate or severe hepatic impairment compared with demographically matched healthy participants with normal hepatic function.

**Genentech, Inc.**
Sponsor

**Phase 1**
Phase

**NCT07144111 GP45942**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years & # 80 Years | Accepts Healthy Volunteers |

## *Inclusion Criteria:*

All participants:

- Body Mass Index 18.0 to 40.0 kilogram per meter square (kg/m^2), inclusive, and body weight >=45 kg.
- Negative hepatitis B surface antigen (HBsAg) test
- Positive hepatitis B surface antibody (HBsAb) test or negative HBsAb
- Negative HIV (Human Immunodeficiency Virus) test

- Females will not be pregnant or breastfeeding and must be either postmenopausal or surgically sterile
- Males will agree to use contraception and will refrain from sperm donation

Healthy participants (Cohort 1):

- Negative hepatitis C virus (HCV) antibody test or positive HCV antibody test followed by a negative HCV RNA test
- Normal hepatic function and no history of clinically significant hepatic dysfunction

Participants with Hepatic Impairment (Cohorts 2 and 3):

- Considered to have moderate (Child-Pugh score of 7 to 9) or severe (Child-Pugh score of 10 to 15) hepatic impairment
- Chronic, stable hepatic insufficiency with features of cirrhosis
- Negative hepatitis C viral load

## *Exclusion Criteria:*

All participants:

- History of Type 1 diabetes or Type 2 Diabetes that is insulin-dependent or requires ongoing systemic treatment with two or more agents
- Significant history or clinical manifestation of any metabolic, allergic, dermatological, renal, hematological, pulmonary, cardiovascular, gastrointestinal (GI), neurological, or psychiatric disorder
- Significant illness, surgery, or hospitalization within 2 weeks prior to dosing.
- History of gastro-intestinal surgery
- Malabsorption syndrome or any other condition that would interfere with enteral absorption.
- History of active or latent Mycobacterium tuberculosis (TB), regardless of treatment history, or positive QuantiFERON® TB Gold test
- History of significant hypersensitivity, intolerance, or allergy to any drug compound, food, or other substance
- Use of drugs of abuse (including opioids)

Healthy participants (Cohort 1):

- History of alcoholism or drug addiction

Participants with Hepatic Impairment (Cohorts 2 and 3):

- Hepatic impairment due to hepatocellular carcinoma or bile duct cancer
- Surgical or artificial portosystemic shunt (e.g., transjugular intrahepatic portosystemic shunt)
- Evidence of hepatorenal syndrome
- Ascites requiring paracentesis
- Any evidence of progressive liver disease in the last 1 month
- Receipt of a liver transplant
- Hepatic encephalopathy Grade 2 or above