

# ForPatients

by Roche

Hepatic Insufficiency Hepatitis B Virus Liver Failure

## A Study of Ipatasertib in Participants With Mild, Moderate or Severe Hepatic Impairment Compared to Healthy Participants

**Trial Status**  
Completed

**Trial Runs In**  
1 Country

**Trial Identifier**  
NCT03341884 GP40200

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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 Pharmacokinetics and Safety of Ipatasertib in Subjects With Mild, Moderate or Severe Hepatic Impairment Compared to Healthy Subjects

### Trial Summary:

This is a Phase 1 study evaluating the pharmacokinetics, tolerability and safety of a single dose of ipatasertib in participants with mild, moderate or severe hepatic impairment compared to healthy participants.

**Genentech, Inc.**  
Sponsor

**Phase 1**  
Phase

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**NCT03341884 GP40200**  
Trial Identifiers

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### Eligibility Criteria:

**Gender**  
All

**Age**  
# 18 Years & # 74 Years

**Healthy Volunteers**  
Accepts Healthy Volunteers

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### Inclusion Criteria:

- In good health (except for specific inclusion criteria related to hepatic impairment), as determined by the Investigator, based on no clinically significant findings from medical history, physical examination, 12-lead electrocardiogram, and vital signs
- Females will not be pregnant or breastfeeding, and must be either postmenopausal or agree to use a study-approved method of contraception from the time of signing the informed consent until 30 days after discharge

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- Males will either be sterile or agree to use male condom with spermicide from check-in (Day -1) until 90 days following the dose of study drug

## Additional Inclusion Criteria for Healthy Subjects Only:

- Liver enzyme tests must be less than or equal to the upper limits of normal

## Additional Exclusion Criteria for Hepatic Impaired Subjects Only:

- Hepatic impairment must have a Child-Pugh score of 5 to 6 (mild), 7 to 9 (moderate), or 10 to 15 (severe) and have stable hepatic insufficiency within 1 month prior to Screening

## ***Exclusion Criteria:***

- History of ulcerative colitis or stomach or intestinal surgery or resection
- History of unstable diabetes mellitus
- History of alcoholism or drug addiction within 1 year prior to Check-in (Day -1)
- Use of oral, implantable, transdermal, or injectable contraceptives from the time of signing the informed consent (females only) or 10 days prior to Check-in through 45 days after the dose administration
- Poor peripheral venous access
- Receipt of blood products within 2 months prior to check-in

## Additional Exclusion Criteria for Healthy Subjects Only:

- Use of any tobacco- or nicotine-containing products within 6 months prior to check-in and during the entire study
- Significant history or clinical manifestation of any metabolic, allergic, dermatological, hepatic, renal, hematological, pulmonary, cardiovascular, gastrointestinal, neurological, or psychiatric disorder

## Additional Exclusion Criteria for Hepatic Impaired Subjects Only:

- Any evidence of progressive liver disease that has worsened or is worsening within 1 month prior to the screening visit
- Participant has shown evidence of hepatorenal syndrome
- Ascites requiring paracentesis
- Participant has required treatment for GI bleeding within 12 months prior to Check-in
- Participant has required additional medication for hepatic encephalopathy within the 12 months (6 months for severe hepatic impairment) prior to check-in
- Total bilirubin levels >6 mg/dL