ForPatients
by Roche

Liver Failure

A Study to Evaluate the Pharmacokinetics of Divarasib in Healthy Participants and Participants With Impaired Hepatic Function

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT06734208 GP45713

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase 1, Open-Label, Single-Dose, Parallel-Cohort Study to Evaluate the Pharmacokinetics of Divarasib in Subjects With Impaired Hepatic Function

Trial Summary:

This is a phase 1, open-label, single-dose, parallel-cohort study to determine the pharmacokinetics (PK) of divarasib in healthy participants and participants with varying degrees of hepatic impairment, as defined by Child-Pugh classification.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT06734208 GP45713
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Males or females of non-childbearing potential
- Within body mass index (BMI) range of 18.0 to 45.0 kg/m2

Participants with Hepatic Impairment

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- Considered to have mild, moderate, or severe hepatic impairment by Child-Pugh Score classification and has been clinically stable for at least 1 month prior to Screening
- Chronic (>6 months), stable hepatic insufficiency with features of cirrhosis due to any etiology. Participants must also remain stable throughout the Screening period

Exclusion Criteria:

- Significant history or clinical manifestation of any metabolic, allergic, dermatological, hepatic, renal, hematological, pulmonary, cardiovascular, gastrointestinal (GI), neurological, or psychiatric disorder
- History of significant hypersensitivity, intolerance, or allergy to any drug compound, food, or other substance, unless approved by the investigator

Participants with Hepatic Impairment

- Have a QTcF >480 msec for males and >490 msec for females at Screening or Check-in. If any parameter is out of range, the ECG may be repeated for confirmation
- Any evidence of progressive liver disease that has worsened or is worsening, as determined by the investigator, within 1 month prior to Screening
- Demonstrated evidence of hepatorenal syndrome
- Ascites requiring paracentesis or other intervention up to 3 days prior to the study
- Hepatic encephalopathy Grade 2 or above

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