ForPatients
by Roche

Non Alcoholic Steato-HepatitisMetabolic dysfunction-associated steatohepatitis (MASH)

A Study to Evaluate the Efficacy and Safety of Pegozafermin in Participants With Compensated Cirrhosis Due to MASH

Trial Status	Trial Runs In	Trial Identifier
Recruiting	25 Countries	NCT06419374 GC46898 BIO89-100-132

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 3 Study to Evaluate the Efficacy and Safety of Pegozafermin in Subjects With Compensated Cirrhosis Due to Metabolic Dysfunction-Associated Steatohepatitis (MASH) (ENLIGHTEN-Cirrhosis)

Trial Summary:

The study will assess the efficacy and safety of pegozafermin administered in participants with biopsy-confirmed and clinically confirmed compensated cirrhosis due to MASH .

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT06419374 GC46898 BIO89-100-132
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

Inclusion Criteria:

- Males or non-pregnant females aged between 18 and 75 years (inclusive) at time of signing the informed consent form (ICF).
- Participants must have type 2 diabetes mellitus diagnosed at least 3 months before screening or at least 2 metabolic risk factors.
- Evidence of both cirrhosis and MASH etiology, either through a historical biopsy or a biopsy at Screening.
- Clinical diagnosis of cirrhosis based on the NIT algorithm.

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Exclusion Criteria:

- Liver disorder other than MASH.
- History or evidence of hepatic decompensation.
- History or evidence of hepatocellular carcinoma.
- Have type 1 diabetes mellitus or poorly controlled type 2 diabetes mellitus.
- ALT or aspartate aminotransferase (AST) #250 units per liter (U/L).
- Participants taking vitamin E (>400 international units [IU]/day) must be on stable dose for at least 6 months prior to screening.

Other protocol-defined inclusion and exclusion criteria may apply.

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