ForPatients
by Roche

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

A Study Evaluating the Efficacy and Safety of Pegozafermin in Participants With MASH and Fibrosis (ENLIGHTEN-Fibrosis)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	27 Countries	NCT06318169 GC46896 BIO89-100-131

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 Metabolic Dysfunction-Associated Steatohepatitis (MASH) and Fibrosis

Trial Summary:

The study will assess the efficacy and safety of 2 dose regimens of pegozafermin compared to placebo for the treatment of liver fibrosis stage F2 or F3 in adult participants with MASH.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT06318169 GC46896 BIO89-100-131
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 80 Years	No

Inclusion Criteria:

- Males or non-pregnant females aged between 18 and 80 years (inclusive) at time of signing the informed consent form (ICF)
- Biopsy-confirmed MASH with fibrosis stage F2 or F3
- Body mass index (BMI) at screening #25.0 kilograms (kg)/meters squared (m^2) (#23 kg/m^2 for Asian participants).

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Exclusion Criteria:

- Chronic liver diseases other than MASH
- Evidence of cirrhosis on screening liver biopsy
- Have type 1 diabetes or poorly controlled type 2 diabetes
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) #250 units per liter (U/L)
- Participants taking vitamin E (>400 international units [IU]/day) or pioglitazone must be on stable dose for at least 6 months prior to Screening

Other inclusion and exclusion criteria may apply.

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