ForPatients
by Roche

Metabolic dysfunction-associated steatohepatitis (MASH)

A Study to Assess the Safety, Pharmacokinetics, and Activity of RO7790121 in Participants With Advanced MASH Liver Fibrosis

Trial Status	Trial Runs In	Trial Identifier
Recruiting	3 Countries	NCT06903065 CC45687

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 Ib, Multicenter, Open-Label, Single-Arm Study to Assess the Safety, Pharmacokinetics, and Activity of RO7790121 in Patients With Advanced MASH Liver Fibrosis

Trial Summary:

The purpose of this study is to assess the safety, pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity and activity of RO7790121 in participants with advanced metabolic dysfunction-associated steatohepatitis (MASH) fibrosis.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT06903065 CC45687
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Body mass index within the range of >= 25 and <=45 kilograms per square meter (kg/m^2)
- MASH with fibrosis score of F3 or F4 confirmed by transient elastography measurement >=12.0 kPa and <=25.0 kPa
- Agreement to adhere to the contraception requirements

Exclusion Criteria:

- Weight gain or loss >5% in the 3 months prior to baseline or >10% in the 6 months prior to baseline
- Bariatric surgery within 1 year prior to baseline
- Current signs or prior history of decompensated liver disease
- Complications or clinical evidence of portal hypertension
- Lack of peripheral venous access
- Other causes of liver disease based on medical history and/or centralized review of liver histology
- History of liver transplantation
- Current or prior history of hepatocellular carcinoma (HCC)
- Uncontrolled hypertension
- Concomitant Type 1 diabetes, or Type 2 diabetes with HbA1c >10%
- History of malignancy within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Current, significant alcohol consumption or a history of significant alcohol consumption for a period of more than 3 consecutive months any time within 1 year prior to screening
- Initiation of a medication of an antidiabetic, weight loss, lipid-modifying or anti-depressant drug class
- Active tuberculosis requiring treatment within the 12 months prior to baseline
- History of organ transplant