

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

NCT06419374

Status	RECRUITING
Phase	Phase 3
Sponsor	89bio, Inc.
Enrollment	762 participants

Key Eligibility Criteria

Inclusion (4)

- 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.
- Biopsy-confirmed fibrosis stage F4 MASH (NASH Clinical Research Network (CRN) system) with compensated cirrhosis.
- Body mass index (BMI) at screening ≤ 25.0 (≤ 23.0 for Asian participants) and < 50.0 kilograms (kg)/meters squared (m^2).

Exclusion (6)

- 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).

... and 1 more (see full listing online)

Locations (291 total)

89bio Clinical Study Site, Birmingham, Alabama, United States

89bio Clinical Study Site, Homewood, Alabama, United States

89bio Clinical Study Site, Chandler, Arizona, United States

... and 288 more locations