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

NCT06318169

Status	RECRUITING
Phase	Phase 3
Sponsor	89bio, Inc.
Enrollment	1,350 participants

Key Eligibility Criteria

Inclusion (3)

- 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 e25.0 kilograms (kg)/meters squared (m\^2) (e23 kg/m\^2 for Asian participants).

Exclusion (5)

- 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) e250 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

Locations (331 total)

89bio Clinical Study Site, Birmingham, Alabama, United States
89bio Clinical Study Site, Chandler, Arizona, United States
89bio Clinical Study Site, Flagstaff, Arizona, United States
... and 328 more locations

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