A Study to Evaluate ALN-CIDEB in Adult Participants With Metabolic Dysfunction-Associated Steatotic Liver Disease or With Metabolic Dysfunction-Associated Steatohepatitis (MASLD/MASH)

NCT06836609

Status	RECRUITING
Phase	Phase 1
Sponsor	Regeneron Pharmaceuticals
Enrollment	132 participants

Key Eligibility Criteria

Inclusion (7)

- Part A: 18 to 55 years at Screening Visit 1 with MASLD, at Screening Visit 1 Part B: 18 to 65 years at Screening Visit 1 with a diagnosis of MASH, at Screening Visit 1
- Body Mass Index (BMI) e30 kg/m2 and d40 kg/m2 at Screening Visit 1
- Controlled-Attenuation Parameter (CAP) e285 dB/m by FibroScan during screening as described in the protocol
- Liver fat content e8.5% by MRI-PDFF during screening
- If on anti-hypertensive and/or lipid lowering medications and/or glucose lowering medications, must be on generally stable dose(s) for at least 12 weeks prior to screening and no changes to the dose(s) are anticipated during the study

... and 2 more (see full listing online)

Exclusion (9)

- Known historical or current diagnosis of portal hypertension or cirrhosis based on clinical assessment, imaging, and/or liver biopsy
- Known historical or current diagnosis of other forms of chronic liver disease, as defined in the protocol
- Prior or current suspected or known drug-induced liver injury within 1 year prior to screening
- History of liver transplant, current placement on a liver transplant list, or Model for End-stage Liver Disease (MELD) score \>12
- Contraindication to MRI examinations, such as persons with cardiac pacemaker and implants made of metal, severe claustrophobia, size restrictions, or other contraindications for MRI

... and 4 more (see full listing online)

Locations (2 total)

Richmond Pharmacology Limited, London, Greater London, United Kingdom
Parexel International Early Phase Clinical Unit, Harrow, London, United Kingdom