A Phase 3 Study to Evaluate the Efficacy and Safety of MGL-3196 (Resmetirom) in Patients With NASH and Fibrosis

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Must be willing to participate in the study and provide written informed consent. 2. Male and female adults ≥ 18 years of age. 3. Suspected or confirmed diagnosis of NASH 1. Metabolic risk factors and AST > 20 U/L 2. Criteria consistent with liver fibrosis as defined as one of the following:

• Biochemical test for fibrosis OR

• Fibroscan test OR

• Historical liver biopsy with diagnosis of NASH with fibrosis Stage 2 or 3 4. MRI-PDFF with increased fat fraction 5. Biopsy-proven NASH (Baseline liver biopsy) based on a liver biopsy obtained within 24 weeks before anticipated date of randomization (if the biopsy is deemed acceptable for interpretation by the central reader) with fibrosis stage 1A, 1B, 2, or 3 on liver biopsy and NAS of ≥ 4 with a score of at least 1 in each of the following NAS components: 1. Steatosis (scored 0 to 3) 2. Ballooning degeneration (scored 0 to 2) 3. Lobular inflammation (scored 0 to 3)

Exclusion Criteria:

1. History of significant alcohol consumption for a period of more than 3 consecutive months within 1 year prior to Screening. 2. Regular use of drugs historically associated with NAFLD 3. History of bariatric surgery or intestinal bypass surgery within the 5 years prior to randomization or planned during the conduct of the study. 4. Recent significant weight gain or loss 5. HbA1c ≥ 9.0%. 6. Glucagon-like peptide 1 [GLP-1] agonist, high dose Vitamin E (> 400 IU/day), or pioglitazone therapy unless stable dose for 24 weeks prior to biopsy. 7. Presence of cirrhosis on liver biopsy defined as stage 4 fibrosis. 8. Diagnosis of hepatocellular carcinoma (HCC). 9. MELD score ≥12, as determined at Screening, unless due to therapeutic anti coagulation. 10. Hepatic decompensation 11. Chronic liver diseases other than NASH 12. Active autoimmune disease 13. Serum ALT > 250 U/L. 14. Active, serious medical disease with a likely life expectancy < 2 years. 15. Participation in an investigational new drug trial in the 60 days or 5 half-lives, whichever is longer. 16. Any other condition which, in the opinion of the Investigator, would impede compliance, hinder completion of the study, compromise the well-being of the patient, or interfere with the study outcomes.

Conditions & Interventions

Interventions:
Drug: MGL-3196, Drug: Placebo
Conditions:
NASH - Nonalcoholic Steatohepatitis

More Information

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IRB
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