

A Study to Evaluate the Use of Resmetirom in Participants With MASLD and HIV

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Adults (≥ 18 years of age) with documented HIV. 2. Documented diagnosis of MASLD established by imaging (ultrasound, CT scan or MRI) or vibration-controlled transient elastography (VCTE) or liver biopsy within 12 months before screening. 3. Hepatic fat fraction $\geq 8\%$ by MRI-PDFF. 4. Liver stiffness by VCTE ≥ 8 kPa and CAP ≥ 263 dB/m. 5. HIV-1 RNA < 200 copies/mL for ≥ 6 months on antiretroviral therapy (ART) (must have screening HIV-1 RNA value and one clinical care value within 6 months prior to screening and up to the randomization that meet the criteria). 6. Stable ART regimen for ≥ 3 months prior to screening and stable up to the randomization and no active plans to change ART while on study. 7. Willingness to participate in the study.

Exclusion Criteria:

1. History of significant alcohol consumption (defined as > 2 drinks/day on average for men, > 1 drinks/day on average for women) for at least 3 consecutive months (12 consecutive weeks) within 5 year before screening. 2. History of other acute or chronic liver disease, including, but not limited to autoimmune, primary biliary cholangitis, Wilson's disease, alpha 1 antitrypsin deficiency, hemochromatosis, hepatitis B virus (HBV), and ongoing or recent (within the past 3 years) hepatitis C RNA positivity. 3. History of liver transplant. 4. Liver biopsy or radiologic imaging consistent with the clinical presence of cirrhosis or portal hypertension at screening. 5. Participants whose Visit 2 ALT, AST, or alkaline phosphatase (ALP) values exceed their Visit 1 values by more than 50%. 6. Inability to undergo MRI testing. 7. Uncontrolled T2DM defined as glycated hemoglobin (HbA1c) $> 9.5\%$ at screening. 8. Any of the following laboratory values at screening: 1. ALT or AST > 250 U/L. 2. Total bilirubin (TBL) > 1.5 mg/dL and direct bilirubin > 0.5 mg/dL (unless due to Gilbert's disease or atazanavir use, per the opinion of the site investigator). 3. Platelet count $< 150,000/\text{mm}^3$. 4. Estimated glomerular filtration rate (e-GFR) < 60 mL/min/1.73m² using the chronic kidney disease-epidemiology collaboration (CKD-EPI) equation. 5. International normalized ratio (INR) > 1.3 . 6. Albumin < 3.6 g/dL. 9. Liver stiffness measurement (LSM) by VCTE > 20 kPa. 10. Further exclusion criteria apply.

Conditions & Interventions

Interventions:

DRUG: Resmetirom, DRUG: Placebo Control

Conditions:

MASLD - Metabolic Dysfunction-Associated Steatotic Liver Disease, HIV (Human Immunodeficiency Virus)

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT07143968

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