LIVERAGE™ - Cirrhosis: A Study to Test Whether Survodutide Helps People With a Liver Disease Called NASH/MASH Who Have Cirrhosis

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion criteria: 1. Male or female adults ≥18 years of age at the time of screening, and at least the legal age of consent in countries where it is \>18 years 2. Body mass index (BMI) ≥27 kg/m2(≥25 kg/m2 for Asian trial participants) 3. Compensated metabolic dysfunction-associated steatohepatitis (MASH) cirrhosis. 4. Magnetic resonance imaging proton density fat fraction (MRI-PDFF) fat fraction ≥5% or FibroScan® with controlled attenuation parameter (CAP) ≥288 dB/m, obtained during the screening period or a historic MRI-PDFF ≤12 weeks prior to randomisation (except for patients with 'cryptogenic cirrhosis' where MRI-PDFF \<5% or FibroScan® with CAP \<288 dB/m is allowed). This inclusion criterion does not apply for participants with a recent (≤12 months prior to randomisation) liver biopsy showing steatosis/steatohepatitis. 5. Further inclusion criteria apply. Exclusion criteria: 1. Current or history (\<5 years) of significant alcohol consumption, defined as an average of \>140 g/week in female patients and \>210 g/week in male patients, for a period of \>3 consecutive months, or an inability to reliably quantify alcohol consumption based upon judgment of the investigator. 2. Model of end-stage liver Disease (MELD) score \>12 due to liver disease 3. History or current (i.e. at screening) hepatic decompensation event of any of the following but not limited to: * Portal hypertension-related upper gastrointestinal (GI) bleeding * Ascites * Hepatic encephalopathy (HE) ≥Grade 1 according to the West Haven criteria 4. Any of the following lab test result at screening * Albumin below \<3.5 g/dL (\<35.0 g/L) * International normalised ratio (INR) \>1.3 unless due to therapeutic anticoagulants * Total bilirubin (TBL) \>1.2x upper limit of normal (ULN) NOTE: Trial participants with Gilbert Syndrome are eligible with a TBL \>1.2x ULN if reticulocyte count is within normal limits, haemoglobin is within normal limits unless due to chronic anaemia and unrelated to haemolysis, and direct bilirubin is \<20% of TBL. * Alkaline phosphatase \>1.5x ULN * PLT \<100,000/µL (\<100 GI/L) 5. History or evidence of other chronic liver diseases, such as primary biliary cholangitis, primary sclerosing cholangitis, autoimmune hepatitis or overlap syndrome, Wilson's disease, alpha-1-antitrypsin deficiency, or genetic haemochromatosis 6. Hepatitis B positive (defined as positive hepatitis B surface antigen (HBsAg)) or history of chronic HBV infection 7. Hepatitis C positive (defined as positive hepatitis C virus (HCV) antibody and a positive HCV ribonucleic acid (RNA)) 8. Serum aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) \>5x ULN 9. Evidence of alcoholic liver disease, or drug-induced liver disease, as defined on the basis of typical exposure and history 10. History of liver transplantation or listed for liver transplantation 11. History of transjugular intrahepatic portosystemic shunt (TIPS) or other radiological/surgical procedure for portal hypertension treatment 12. Further exclusion criteria apply

Conditions & Interventions

Interventions:

COMBINATION_PRODUCT: Survodutide, COMBINATION_PRODUCT: Placebo matching survodutide

Conditions:

Metabolic Dysfunction Associated Steatohepatitis

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT06632457