LIVERAGE™: A Study to Test Whether Survodutide Helps People With a Liver Disease Called NASH/MASH Who Have Moderate or Advanced Liver Fibrosis

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion criteria: 1. Male or female participants ≥18 years (or who are of legal age in countries where that is greater than 18 years) of age at time of consent 2. Diagnosis of MASH (non-alcoholic fatty liver disease (NAFLD)) activity score \[NAS\] ≥4 3. Stable body weight defined as less than 5% self-reported change in body weight 3 months prior to the screening or during the period between the historical biopsy and randomisation, if a historical biopsy is used 4. Be willing to maintain a stable diet and physical activity levels throughout the entire trial Further inclusion criteria apply Exclusion criteria: 1. Any of the following liver laboratory test abnormalities at screening: * Serum AST and/or alanine aminotransferase (ALT) elevation ≥5x upper limit of normal (ULN) * Platelet count \<140 000/mm\^3 (\<140 GI/L) * Alkaline phosphatase \>2x upper limit of normal (ULN) * Abnormal synthetic liver function as defined by screening central laboratory evaluation: * Albumin below \<3.5 g/dL (35.0 g/L) * OR International normalised ratio (INR) of prothrombin time \>1.3 * OR total serum bilirubin concentration ≥1.5x ULN 2. Any history or evidence of acute or chronic liver disease other than MASH 3. Histologically documented liver cirrhosis (fibrosis stage F4), either at screening or in a historical biopsy 4. History of or current diagnosis of hepatocellular carcinoma 5. History of or planned liver transplant 6. Inability or unwillingness to undergo a liver biopsy at screening (if a suitable historical biopsy is unavailable for central review), or during trial conduct. 7. History of portal hypertension or presence of decompensated liver disease 8. Model for end-stage liver disease (MELD) score ≥12 due to liver disease. Further exclusion criteria apply

Conditions & Interventions

Interventions:

COMBINATION_PRODUCT: Survodutide, COMBINATION_PRODUCT: Placebo

Conditions:

Metabolic Dysfunction Associated Steatohepatitis (MASH), Liver Fibrosis

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT06632444