FXR Effect on Severe Alcohol-Associated Hepatitis (FRESH) Study

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 65 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Males or females aged 18 to 65 years (inclusive) 2. Clinical diagnosis of sAH based on all the following: 1. History of ongoing excess alcohol (\>60 g/day \[male\] or \>40 g/day \[female\]) use for ≥6 months, with \<60 days of abstinence prior to the onset of jaundice 2. Serum total bilirubin \>3.0 mg/dL 3. Aspartate aminotransferase (AST) ≥50 U/L 4. AST/Aspartate aminotransferase (ALT) ratio ≥1.5 5. Onset of jaundice within prior 8 weeks 6. Cohort 1 through Cohort 4: Maddrey's Discriminant Factor (mDF) ≥32 and ≤70 7. Cohort 5 and Cohort 6: mDF ≥32 3. Cohort 1 through Cohort 4: MELD score ≥18 to ≤25 (inclusive) and Cohort 5 and Cohort 6: MELD score ≥21 to ≤30 4. Female participants must be postmenopausal, surgically sterile, or, if premenopausal (and not surgically sterile), be prepared to use ≥1 highly effective method of contraception from the initiation of Screening and for 90 days after the last dose of investigational product as follows: * Surgical sterilization (bilateral tubal occlusion, etc.) * Placement of an intrauterine device (IUD) or intrauterine system (e.g., intrauterine hormone-releasing system \[IUS\]) * Combined (estrogen and progesterone containing) hormonal contraceptive associated with inhibition of ovulation: * Oral * Intravaginal * Transdermal * Progesterone-only hormonal contraception associated with inhibition of ovulation: * Oral * Injectable * Implantable * Sexual abstinence: When in line with the preferred and usual lifestyle of the participant, is defined as avoiding all types of activity that could result in conception (pregnancy) from the initiation of Screening and until at least 90 days after the last dose of investigational product 5. Male participants who are sexually active with female partners of childbearing potential must agree to use a condom with spermicide and to use 1 other approved method of highly effective contraception from the initiation of Screening and until at least 90 days after the dose of investigational product as listed in Inclusion Criteria #3. 6. Male participants must refrain from sperm donation from the initiation of Screening and until at least 90 days after the last dose of investigational product 7. Must provide written informed consent and agree to comply with the study protocol. In participants with hepatic encephalopathy which may impair decision-making, consent will be obtained per hospital procedures (e.g., by Legally Authorized Representative). 8. Participants must agree to participate in an alcohol use disorder program during the study period, as recommended by the local institution's addiction medicine specialists, including post-hospitalization

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Exclusion Criteria:

1. Participants taking products containing obeticholic acid in the 30 days prior to randomization 2. Participants taking \>2 doses of systemic corticosteroids within 30 days prior to randomization. 3. Participants who have been inpatient at a referral hospital for \>7 days prior to transfer. 4. Pregnancy, planned pregnancy, potential for pregnancy (e.g., unwillingness to use effective birth control during the study), or current or planned breast feeding. 5. Abstinence from alcohol consumption for \>2 months before Day 1. 6. AST or ALT \>400 U/L. 7. Cohort 1 through Cohort 4: mDF \<32 or \>70. 8. Cohort 5 and Cohort 6: mDF \<32 9. Cohort 1 through Cohort 4: MELD score \<18 or \>25. 10. Cohort 5 and Cohort 6: MELD \<21 or \>30 11. Other causes of liver disease including chronic hepatitis B (hepatitis B surface antigen \[HBsAg\] positive), chronic hepatitis C virus (HCV) RNA positive, drug-induced liver injury (DILI), biliary obstruction, and autoimmune liver disease. 12. Current or previous history of hepatocellular carcinoma (HCC) 13. History of liver transplantation or currently listed for liver transplant 14. Untreated infection (e.g., has not initiated appropriate medical treatment for infection) 15. Known positivity for human immunodeficiency virus infection 16. Uncontrolled gastrointestinal (GI) bleeding or controlled GI bleeding that was associated with shock or required transfusion of more than 3 units of blood within 7 days of Screening. 17. Kidney injury defined as a serum creatinine \>133 µmol/L (\>1.5 mg/dL) or the requirement for renal replacement therapy whether prior to or after study screening. 18. Portal vein thrombosis 19. Acute pancreatitis or acute gallbladder disease (e.g., cholecystitis) 20. Severe, on-going associated disease (e.g., cardiac failure, acute myocardial infarction, severe cardiac arrhythmias, severe pulmonary disease, neurologic disease) 21. Malignancy within the 2 years prior to Screening, with the exception of specific cancers that have been cured by surgical resection (e.g., basal cell skin cancer). Participants under evaluation for possible malignancy are not eligible. 22. Positive urine drug screen (amphetamines, barbiturates, benzodiazepines, cocaine, and opiates) except tetrahydrocannabinol or in the setting of documented prescription medications (e.g., opiates, benzodiazepines, amphetamines, barbiturates), which also include medications prescribed as part of in-patient management. Participants being treated for alcohol withdrawal may be exempt for this reason, verify with Medical Monitor. 23. Participated in a clinical research study and received any active investigational product being evaluated for the treatment of sAH within 3 months before Day 1 24. Participation in a study of another investigational medicine or device within 30 days before Screening 25. Any other condition or clinical laboratory result that, in the opinion of the Investigator, might confound the results, or would impede compliance or hinder completion of the study 26. Participants treated in the Dose Escalation Phase (Cohort 1 through Cohort 4) are not eligible for enrollment into an Extension Cohort (Cohort 5 and Cohort 6), and participants treated in Cohort 5 are not eligible for enrollment into Cohort 6.

Conditions & Interventions

Interventions:
DRUG: INT-787, DRUG: Placebo
Conditions:
Alcohol Associated Hepatitis
Keywords:
Severe Alcohol associated Hepatitis (sAH), Alcoholic Hepatitis (AH), Hepatitis, Alcoholic

More Information

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