Efficacy, Safety and Tolerability of VS-01 in Adult Patients With Acute-on-Chronic Liver Failure and Ascites (UNVEIL-IT)®

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 79 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Patients with ACLF Grade 1, 2, or 3a according to European Association for the Study of the Liver (EASL)-CLIF criteria; 2. Onset of ACLF not more than 14 days before Baseline (BL); 3. Presence of ascites requiring diagnostic or therapeutic paracentesis; 4. Patients with dry body weight ≥40 and \<140 kg; 5. Written informed consent obtained prior to the start of any study-related procedures.

Exclusion Criteria:

1. Presence of any of the following organ failure(s) as per the EASL-CLIF criteria and/or adapted from CLIF-C Organ Failure (CLIF-C OF)/CLIF- Sequential Organ Failure Assessment (CLIF-SOFA) scores: 1. Respiratory failure necessitating invasive mechanical ventilation; 2. Coagulation failure (INR \> 3.2 or platelet count ≤20 x 109/L); 3. Severe cardiovascular failure requiring the use of high dose vasopressors; 2. ACLF grade 3b: Presence of four or more organ failures as per EASL CLIF criteria; 3. Presence of spontaneous or secondary bacterial peritonitis; 4. Presence of uncontrolled severe infection(with hemodynamic instability or shock); 5. Poorly controlled seizure disorder; 6. Patients with history of upper gastro-intestinal bleeding over the past 7 days prior to BL, acute bleeding or bleeding upon paracentesis at screening (SCR) or BL; 7. Contraindication for paracentesis; 8. Coagulation disorders such as disseminated intravascular coagulation or hemophilia; 9. Potential or known hypersensitivity to liposomes; 10. Potential or known risk factors for allergic/anaphylactoid like reactions (e.g., mastocytosis/elevated basal tryptase) or multiple hypersensitivities; 11. Patients after organ transplantation receiving immunosuppressive medication; 12. Any severe disease considered to be potentially detrimental at the discretion of the Principal Investigator. This includes but is not limited to hepatocellular carcinoma outside Milan criteria, cholangiocarcinoma, extrahepatic cancer over the past 2 years or people who inject drugs; 13. Need for Renal Replacement Therapy or any extracorporeal liver support device (e.g., MARS®, Prometheus®, plasmapheresis); 14. Alfapump® in place to manage ascites; 15. Pregnancy and lactation; 16. Women of child-bearing potential who are not willing to use adequate contraception; 17. Patients who participate in another clinical trial at the time of SCR or within 4 weeks prior to SCR.

Conditions & Interventions

Interventions:
DRUG: VS-01 on top of SOC, OTHER: SOC (Control Group)
Conditions:
Acute-On-Chronic Liver Failure, Ascites
Keywords:
Chronic liver diseases, Hepatic Dysfunction, Extrahepatic Organ Dysfunction, Liver Failure, Renal Disease, Hepatic Impairment, Renal Impairment, Hepatic Decompensation, Cirrhosis

More Information

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Phase: PHASE2
IRB
Number:
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