A Study of OCE-205 in Participants With Cirrhosis With Ascites Who Developed Hepatorenal Syndrome-Acute Kidney Injury

Status: Recruiting

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Signed informed consent form (ICF) by participant or their legal/authorized representatives.

• Diagnosed with decompensated cirrhosis with ascites.

• Receiving albumin and has had appropriate diuretic withdrawal for at least 2 days prior to randomization into the study.

• Beta-blockers should be discontinued 48 hours prior to randomization, unless doctor deems necessary for appropriate medical treatment.

• No sustained improvement in renal function after both diuretic withdrawal and plasma volume expansion with albumin.

• Female participants must have a negative pregnancy test prior to randomization and agree to avoid becoming pregnant during the study and for 30 days after the end of treatment. Male participants must agree to use 2 effective contraceptive methods during the study and up to 30 days after the end of treatment.

Exclusion Criteria:

• Serum Creatinine >3.8 mg/dL.

• Large volume paracentesis (LVP ≥6L) within 4 days of randomization.

• Pulse oximeter reading of <90% on 2L or less.

• Sepsis and/or uncontrolled bacterial infection.

• Experienced shock within 72 hrs prior to screening.

• Model for End-Stage Liver Disease (MELD) score >35.

• Hypertension with a Systolic BP > 140 mmHg and/ or a Diastolic BP >100 mmHg.

• Treated with or exposed to nephrotoxic agents or has had exposure to radiographic contrast agents within 72 hrs prior to screening.

• Has superimposed acute liver injury due to drugs, or toxins except for acute alcoholic hepatitis.

• Proteinuria greater than 500 mg/dL.

• Impaired cardiac function as evidenced by symptoms consistent with New York Heart Association Classification Class 2 or worse.

• Received Renal Replacement Therapy (RRT) within 4 weeks of randomization.

• Has had a Trans Jugular Intrahepatic Porto-systemic shunt (TIPS).

• Pregnant or breastfeeding.

• Diagnosed with a malignancy within the past 5 years.

• History or current evidence of any condition (COVID-19 positive with respiratory/cardiac complications), therapy or laboratory abnormality that might confound the results of the study, interfere with the participation for the full duration of the study, or is not in the best interest to participate in the opinion of the investigator.

• Participated in a study of an investigational medical product or device within the last 8 weeks preceding screening.

• Experienced a major blood loss (≥500 mL) within the last 4 weeks prior to screening.

• Is stuporous or comatose at screening (West Haven scores III and IV). exhibiting bradycardia.

Conditions & Interventions

Interventions:
Drug: OCE-205, Drug: Placebo
Conditions:
Cirrhosis, Ascites, Hepatorenal Syndrome, Acute Kidney Injury
Keywords:
HRS-AKI

More Information

Contact(s): Clinical Operations - clinicaltrials@ocelotbio.com
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Phase: Phase 2
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