A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of
Evinacumab in Patients with Severe Hypertriglyceridemia for the Prevention of Recurrent Acute
Pancreatitis

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over
This study is NOT accepting healthy volunteers
Key

Inclusion Criteria:

1. Adults without FCS due to LPL loss of function mutations 2. Documented history of 1 HTG-associated AP episode within 24 months of screening 3. Fasting serum TG value >880 mg/dL (10 mmol/L) or >500 mg/dL (5.6mmol/L) determined during the screening period as described in the protocol 4. Stable dose of lipid-lowering therapy (â‰¥8 weeks) and willingness to maintain a stable regimen throughout the study 5. Body mass index â‰¥18.0 and â‰¤45.0 kg/m2 6. Compliance with a stable diet and exercise regimen at screening and willingness to continue the diet through the end of the study Key

Exclusion Criteria:

1. Hospitalization for AP within 4 weeks of screening 2. Known genetic FCS defined as homozygous or compound heterozygous LoF mutations in LPL as defined in the protocol 3. Symptomatic gallstone disease within 6 months prior to screening as defined in the protocol 4. Use of any medication or nutraceutical known to alter serum lipids which has not been part of a stable therapeutic regimen for at least 8 weeks, and there are no plans to change the regimen during the study 5. Presence of any clinically significant, uncontrolled endocrine disease known to influence serum lipids as defined in the protocol 6. Has received a COVID-19 vaccination within 1-week of planned start medication or for which the planned COVID-19 vaccination would not be completed 1-week prior to start of the study Note: Other protocol-defined Inclusion/ Exclusion Criteria apply

Conditions & Interventions

Interventions:
Drug: evinacumab, Other: Placebo
Conditions:
Heart & Vascular, Hypertriglyceridemia
Keywords:
Severe Hypertriglyceridemia (HTG), Recurrent Acute Pancreatitis, Clinics and Surgery Center (CSC)

More Information

Description: The primary objective of the study is to determine the proportion of patients with TG >880 mg/dL, without FCS due to LoF mutations in LPL, and a history of HTG-associated AP who experience a recurrent episode of AP after treatment with evinacumab versus placebo.
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