

CLEAR Outcomes

NCT02993406

Principal Investigator: Dr. Vipin Khetarpal-(S. Washington Office)

Condition: Cardiovascular Diseases; Statin Adverse Reaction

Drug: Bempedoic acid 180 mg tablet vs. Matching placebo tablet

Official Title: A Randomized, Double-blind, Placebo-controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients With, or at High Risk for, Cardiovascular Disease Who Are Statin Intolerant

Sponsor: Esperion Therapeutics, Inc.

Purpose: The purpose of this study is to determine if treatment with bempedoic acid (ETC-1002) versus placebo decreases the risk of cardiovascular events in patients who are statin intolerant.

Inclusion Criteria: Subject Inclusion Criteria:

- Patient reported history of statin intolerance (inability to tolerate 2 or more statins, one at a low dose)
- Men and nonpregnant, nonlactating women
- Fasting blood LDL-cholesterol between 100 and 190 mg/dL at screening
- History of, or at high risk for, cardiovascular disease (CVD) including coronary artery disease, symptomatic peripheral arterial disease, cerebrovascular atherosclerotic disease, or at high risk for a cardiovascular event

Exclusion Criteria:

- Fasting blood triglycerides greater than 500 mg/dL at screening
- Recent history of certain cardiovascular disease including transient ischemic attack (TIA), unstable or symptomatic cardiac arrhythmia, use of an implantable pacemaker or implantable cardioverter defibrillators, or coronary revascularization procedure
- History of heart failure
- Uncontrolled hypertension

Source: <https://clinicaltrials.gov/ct2/show/NCT02993406>

Retrieved on: 7/7/2017