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Patient Care + Research + Clinical Trials

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Obicetrapib in ASCVD with elevated LDL/apoB despite max statin

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Summary: The primary objective is to evaluate the effect of obicetrapib on the risk of major adverse cardiovascular events (MACE), including CV death, non-fatal MI, non-fatal stroke, or non-elective coronary revascularization.
Study location BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2
Hypothesis
Obicetrapib is a monoclonal antibody inhibitor of the enzyme CETP. CETP inhibition results in a rise in HDL (good cholesterol) and a fall in LDL (bad cholesterol) which would be expected to reduce cardiovascular risk, however a previous trial of obicetrapib failed to show benefit. The present study will use a modified protocol to test the same hypothesis that overall cardiovascular risk is reduced. The study will be event-driven and complete after approximately 959 primary endpoint events (ie, CV death, non-fatal MI, non-fatal stroke, or non-elective coronary revascularization) have occurred and after a median treatment duration 48 months.
Eligible Participants include:

- > 18 yrs old
- Established ASCVD
- LDL>/= 2.6 mmol/L and or non HDL C >/=3.4mmol/L and or apoB >/= 0.02 mmol/L
- TG < 4.52 mmol/L
- eGFR > 30
- Stable max tolerated lipid therapies
- A1c < 10%

Treatment course and duration:
The study is designed as a randomized, double-blind, parallel-group, placebo-controlled study that runs for at least 50 months. Participants will be randomized in a 1:1 ratio to receive obicetrapib 10 mg once daily (QD) or matching placebo QD. Treatment allocation will be stratified based on baseline high intensity statin (HIS) use (HIS use or no HIS use). HIS will include rosuvastatin 20 and 40 mg and atorvastatin 40 and 80 mg
Odds of receiving placebo : 1:1 (10 mg obicetrapid or Placebo)
Study documents:

Short URL = https://bit.ly/3uESOj1