

DAL-Outcomes II TRIAL

A Study of Dalcetrapib in Patients with Stable Coronary Heart Disease, with Coronary Heart Disease Risk Equivalents or at Elevated Risk for Cardiovascular Disease

Study Phase: 3b

Purpose

This multicenter, randomized, double-blind, placebo-controlled, parallel-group study with evaluate the potential of dalcetrapib to reduce cardiovascular morbidity and mortality in patients with stable coronary heart disease (CHD), with CHD risk equivalents or at elevated risk for cardiovascular disease. Eligible patients will be randomized to receive either dalcetrapib 600mg orally daily or placebo orally daily, on a background of contemporary, guidelines-based medical care. Anticipated time on study treatment is 4 years.

The study population will include those who meet the following inclusion/exclusion criteria, some of which are:

Inclusion Criteria:

- Male & Females of 45 years old and older
- Established cardiovascular disease A stable coronary disease B cerebrovascular disease C peripheral artery disease
- Without established coronary disease D pharmacologically treated type 2 diabetes mellitus and one more risk factor(s) for cardiovascular disease E 3 or more risk factors for cardiovascular disease
- Receiving evidence-based medical and dietary management of dyslipidemia

Exclusion Criteria:

- Occurrence of myocardial infarction, hospitalization for unstable angina, stroke or revascularization (Coronary, carotid or peripheral) within three months prior to randomization
- Uncontrolled hypertension
- Uncontrolled diabetes
- Concomitant treatment with any other drug raising HDL-C
- Previous treatment with compounds targeting CETP

To inquire if you are eligible for this study or hear more about it, please contact:

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