

ALTITUDE

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Determine Whether, in Patient with Type 2 Diabetes at High Risk for Cardiovascular and Renal Events, Aliskiren, on Top of Conventional Treatment, Reduces Cardiovascular and Renal Morbidity and Mortality.

Study Phase III

Purpose

The purpose of this study is to determine whether, in subjects with type 2 diabetes and pre-existing disease of the heart and the circulatory system and /or the kidney, aliskiren at a target dose of 300mg once daily (compared to placebo), on top of conventional treatment, reduced death and disease caused by the heart, the circulatory system and the kidney.

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

Inclusion Criteria

- Demographics: ≥ 35 years of age.
- Signed & dated, written informed consent to participate in this study.
- Type 2 diabetes and at least one of the following:
 - Macroalbuminuria
 - Microalbuminuria and a reduced kidney function
 - Previous heart attack and a reduced kidney function
 - Previous stroke and a reduced kidney function
 - Heart failure a reduced kidney function
 - Coronary artery disease a reduced kidney function
- Concomitant treatment should follow national guidelines and must include either an Angiotensin-converting-enzyme-inhibitor (ACEi) or an Angiotensin-receptor-blocker (ARB) but not both.

Exclusion Criteria

- Type 1 diabetes mellitus
- Cardiovascular event or procedure ≤ 3 months prior to Visit 1
- Hypertension: Mean sitting systolic blood pressure (msSBP) ≥ 135 and < 170 mmHg or Mean sitting diastolic blood pressure (msDBP) ≥ 85 and < 110 mmHg unless treated with a least 3 anti-hypertensive medications
- Baseline Serum Potassium > 5.0 mmol/L
- Subjects with are treated with two renin-angiotensin-aldosterone-system-blockers
- Subjects with NYHA class III or IV heart failure
- Known renal artery stenosis

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

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