AMGEN LDL STUDY

A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, MULTICENTER STUDY ASSESSING the IMPACT of ADDITIONAL LDL-CHLOESTEROL REDUCTION on MAJOR CARDIOVASCULAR EVENTS when USED in COMBINATION with STATIN THERAPY in PATIENTS with CLINICALLY EVIDENT CARDIOVASCULAR DISEASE

Study Phase III

Purpose

The purpose is that additional LDL-C lowering with AMG 145 when used in addition with other treatment for dyslipidemia is well tolerated and decreases the aggregated risk of cardiovascular death, myocardial infarction, hospitalization for unstable angina, stroke, or coronary revascularization for unstable angina, stroke or coronary revascularization in subjects with clinically evident cardiovascular disease.

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

Inclusion Criteria

- Male or Female $\geq$ 40 to $\leq$ 90 yrs of age
- History of clinically evident cardiovascular disease within 5 yrs of screening as evidence by ANY of the following:
- Diagnosis of myocardial infarction, stroke
- History of type 2 diabetes or, if not diabetic ANY of the following:
- Age $\geq$ 65 yrs (and $\leq$ 80 yrs)
- Additional diagnosis of myocardial infarction or stroke
- History of symptomatic peripheral vascular disease
- $\geq$ 2 of the following risk factors:
- HDL-C < 40 mg/dL for men and < 50 mg/dL for women at screening
- Residual coronary artery disease with $\geq$ 40% stenosis in $\geq$ 2 large vessels
- HsCRP > 2.0 mg/L at screening
- Current smoker
- Age > 60 yrs
- History of non-MI related coronary revascularization
- Final LDL-C $\geq$ 130mg/dL or non HDL-C $\geq$ 160 mg/dL at screening
- Metabolic syndrome defined as $\geq$ 3 of the following:
- Waist circumference > 102 cm for men and > 88 cm for women
- Triglycerides $\geq$ 150 mg/dL at screening
- HDL-C < 40 mg/dL for men and < 50 mg/dL for women at screening
- Blood pressure $\geq$ 130 / $\geq$ 85 mmHg
- Fasting glucose $\geq$ 110 mg/dL by central laboratory at screening
- Fasting LDL-C $\geq$ 70 mg/dL or non-HDL-C $\geq$ 100 mg/dL during screening after $\geq$ 4 weeks of stable dose of 20mg, 40mg, or 80mg QD atorvastatin, with or without ezetimibe 10mg QD
- Fasting triglycerides $\leq$ 400 mg/dL at screening

Exclusion Criteria

- NYHA class III or IV, or last known left ventricular ejection fraction< 30%
- Known hemorrhagic stroke
- Planned or expected cardiac surgery or revascularization within 3 months after randomization
- Uncontrolled hypertension defined as sitting systolic blood pressure > 180mmHg or diastolic BP > 110 mmHg
- In the 6 weeks prior to LDL-C screening, subject has taken red yeast rice, >200 mg/day niacin, or prescription lipid-regulating drugs (eg, bile-acid sequestering resins, fibrates and derivatives) other than statins or ezetimibe

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

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