ORION-11

ASCVD and Risk-Equivalents – Europe (NCT03400800)

COMPLETE
Phase 3 Study

ORION-11 is a pivotal Phase 3, placebo-controlled, double-blind, randomized study to evaluate the efficacy, safety and tolerability of inclisiran sodium 300 mg administered subcutaneously in patients with atherosclerotic cardiovascular disease (ASCVD) or ASCVD-risk equivalents. The primary endpoints are percentage change in LDL cholesterol (LDL-C) from baseline to day 510 (17 months) and time-adjusted percentage change in LDL-C from baseline after day 90 (three months) and up to day 540 (18 months).

PATIENT POPULATION

1,617 participants with ASCVD or ASCVD-risk equivalents and elevated LDL-C, despite maximum tolerated dose of statin therapy (with or without ezetimibe).

LOCATIONS

70 sites in seven countries (ex-U.S.)

STUDY TIMEFRAME

November 2017 – 2019

METHODOLOGY

Each participant will receive one 300-mg dose of inclisiran sodium administered as a subcutaneous injection on day one, again at day 90 (three months) and then every six months thereafter (for a total of four doses over the study duration).

Inclisiran is an investigational drug not yet approved for use by the FDA or any other regulatory authority.

Updated August 2019.