ORION-1

ASCVD – Global (NCT02597127)

COMPLETE
June 2017
Phase 2 Study

ORION-1 is a Phase 2, placebo-controlled, double-blind, randomized trial to evaluate the efficacy, safety and tolerability of inclisiran. The trial compares the effect of different doses of inclisiran and evaluates the potential for an infrequent dosing regimen. The primary endpoint of the trial is the percentage change in LDL cholesterol (LDL-C) from baseline to day 180 (six months).

PATIENT POPULATION

501 randomized participants with atherosclerotic cardiovascular disease (ASCVD) or ASCVD-risk equivalents (e.g., diabetes and familial hypercholesterolemia) and elevated LDL-C despite maximum tolerated dose of LDL-C-lowering therapies.

LOCATIONS

54 sites in five countries

STUDY TIMEFRAME

Jan. 2016 – June 2017

Data from ORION-1 were first presented at the American College of Cardiology's 66th Annual Scientific Sessions in March 2017, and published in the March 17, 2017, online issue of *The New England Journal of Medicine*.

TOPLINE RESULTS

Participants who received inclisiran sodium 300 mg on day one and again at day 90 (three months) met the primary efficacy endpoint of lowering LDL-C by an average of 52.6% (64 mg/dL) at day 180 (six months) with a maximum LDL-C reduction of 54.9% (68 mg/dL) at day 150 (five months). For the six-month period from day 90 (three months) through day 270 (nine months), a time-adjusted mean LDL-C reduction of >50% (63 mg/dL) was observed.

Inclisiran was reported to be well-tolerated, with an overall incidence of adverse events similar to placebo. Most of these events (95%) were mild or moderate in severity (grade 1 or 2). Serious adverse events occurred in 11% of the patients who received inclisiran and in 8% of the patients who received placebo. Injection-site reactions occurred in 5% of the patients who received injections of inclisiran.

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

Updated August 2019.