ORION-8

Extension Study of ORION-5, -9, -10 and -11 Phase 3 Studies (NCT03814187)

ONGOING
Phase 3 Extension Study

ORION-8 is a Phase 3, open-label, long-term extension study of participants from the ORION-5, -9, -10 and -11 studies. The primary endpoints are the proportion of subjects who attain LDL cholesterol (LDL-C) targets of <70 mg/dL for subjects with atherosclerotic cardiovascular disease (ASCVD) risk at the end of the study, and the proportion of subjects who attain LDL-C targets of <100 mg/dL for ASCVD risk equivalent subjects at end of study.

PATIENT POPULATION

Up to 3,700 participants with ASCVD, ASCVD-risk equivalents (e.g., diabetes and familial hypercholesterolemia), or heterozygous or homozygous familial hypercholesterolemia (HeFH or HoFH) and elevated LDL-C despite maximum tolerated dose of LDL-C-lowering therapies who have completed participation in the ORION-5, -9, -10 or -11 clinical trials.

LOCATIONS

Approximately 275 people in 19 countries (with overlap)

STUDY TIMEFRAME

April 2019 – 2023*

METHODOLOGY

Participants will receive one 300-mg dose of inclisiran sodium or corresponding placebo in a blinded manner administered subcutaneously on day one**, then all participants will receive 300 mg of inclisiran sodium at day 90 (three months), and every 180 days (six months) thereafter to day 990 (33 months).

**Subjects who received blinded placebo in their respective study of origin (i.e., ORION-5, -9, -10 or -11) will receive blinded inclisiran, and subjects who received blinded inclisiran in their respective study of origin will receive blinded placebo on day one in ORION-8. Subjects from the open-label ORION-5 study will not receive any injection of study drug/placebo on day one.

** Estimated primary completion date.*

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

Updated August 2019.