ORION-5

Phase 3 Homozygous Familial Hypercholesterolemia (HoFH) (NCT03851705)

ONGOING
Phase 3 Study

ORION-5 is a two-part (double-blind, placebo-controlled/open-label) Phase 3 multicenter study to evaluate the safety, tolerability and efficacy of a 300-mg dose of inclisiran sodium in participants with HoFH. The primary endpoint of the trial is percentage change in LDL cholesterol (LDL-C) from baseline to day 150 (five months).

PATIENT POPULATION

Forty-five participants with a diagnosis of HoFH by genetic confirmation or a clinical diagnosis.

LOCATIONS

15 sites in nine countries;

14 sites in eight countries will recruit to study

STUDY TIMEFRAME

February 2019 – 2021*

METHODOLOGY

Participants in part one of the study will be randomized to receive two 300-mg doses of inclisiran sodium or placebo at day one and day 90 (three months).

Participants in part two of the study will receive a 300-mg dose of inclisiran sodium on day 270 (nine months), day 450 (15 months) and day 630 (21 months) during an open-label, follow-up period.

** 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.