ORION-9

HeFH – Global (NCT03397121)

ONGOING
Phase 3 Study

ORION-9 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 heterozygous familial hypercholesterolemia (HeFH) patients. 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 between day 90 (three months) and up to day 540 (18 months).

PATIENT POPULATION

482 participants with HeFH and elevated LDL-C, despite maximum tolerated dose of LDL-C-lowering therapies (e.g., a statin or ezetimibe). The majority of study participants are taking inclisiran or placebo in addition to existing lipid-lowering therapy with a maximally tolerated statin (with or without ezetimibe).

LOCATIONS

54 sites in eight countries

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).

** Readouts for pivotal Phase 3 studies of inclisiran are expected to start in the second half of 3Q-2019.*

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

Updated August 2019.