ORION-7

Phase 1 Renal Impairment (NCT03159416)

COMPLETE
March 2018
Phase 1 Study

ORION-7 is a completed, Phase 1, single-dose, open-label trial to evaluate the efficacy, safety and tolerability of 300 mg of inclisiran sodium in participants with mild, moderate and severe renal impairment and normal renal function. The primary endpoint of the trial was to determine the pharmacokinetic and pharmacodynamic parameters, as well as safety, of inclisiran in subjects with normal and impaired renal function at 48 hours post-dose. Secondary endpoints include changes from baseline in lipids and lipoproteins, as well as proprotein convertase subtilisin-kexin type 9 (PCSK9), to day 60 (two months).

PATIENT POPULATION
31 participants with mild, moderate and severe renal impairment or normal renal function.

LOCATIONS
Two sites in New Zealand

STUDY TIMEFRAME
June 2017 – March 2018

Data from ORION-7 were first presented at the 87th European Atherosclerosis Society Congress in May 2019.

TOPLINE RESULTS
Participants who received 300 mg of inclisiran sodium achieved consistent reductions in LDL cholesterol (LDL-C) and PCSK9 regardless of renal impairment status at study entry.

Among all patients in the analysis, treatment-emergent adverse event rates were not influenced by renal impairment and were not different from subjects with normal renal function. There was no relationship between inclisiran administration and change in renal function. No dose adjustment of inclisiran is required for patients with renal impairment (mild, moderate or severe), which will allow for subjects with severe renal function to be included in current and future studies of the efficacy and safety of inclisiran.

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

Updated August 2019.