Inhibition Of PCSK9 Synthesis Via RNA Interference: 90-Day Data From Orion-1-a Multi-centre Phase-2 Randomized Controlled Trial

Purpose: To determine long-term safety and efficacy of the RNA interference drug, inclisiran, (targets PCSK9 production), to reduce LDL-C

Trial Design: Phase II, placebo-controlled, randomized, double-blinded, multi-national, multi-center study; 501 patients with elevated LDL-C and ASCVD or at risk for ASCVD randomized to 6 dosing schedules of inclisiran vs. placebo. First SC dose of ALN-PCSSC vs. placebo on day 1. Those randomized to the second dose vs. placebo received it on day 90.

Primary Endpoint: % LDL-C change at 180 days. Interim analysis @ 90 days.

Secondary Endpoint: LDL-C at 90 days

Trial Results ≥ 300 mg dose	LDL-C reduction vs placebo
One dose	50%
Two doses	55-60%

Conclusions: Inhibiting PCSK9 synthesis using inclisiran to target PCSK9 production safely reduced LDL-C at 90 days following a single dose of ALN-PCSSC at baseline. These results suggest that the frequency of these doses could be 2-3 times per year compared to the current monthly or bi-monthly injections needed for PCSK9 inhibitors.

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