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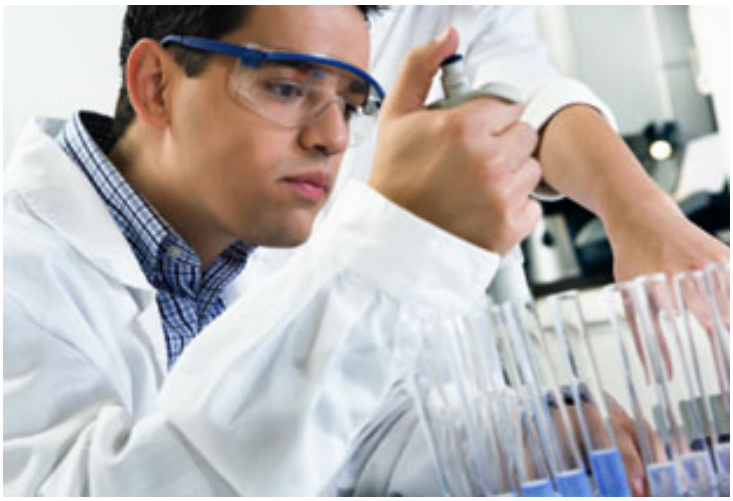

The trials compared the reduction from baseline in low-density lipoprotein cholesterol (LDL-C or 'bad' cholesterol) at 24 weeks with alirocumab versus placebo in patients with hypercholesterolemia.

Alirocumab is an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9).

"In the new monthly dosing trials, Odyssey Choice I and Choice II, the mean percent reduction in LDL-C from baseline was consistent with that seen in previous phase 3 trials evaluating alirocumab every other week dosing," said Dr Bill Sasiela, VP, program direction, cardiovascular and metabolic, Regeneron. "These results continue to validate our clinical development approach, which is designed to investigate various alirocumab doses and intervals to address patients' lipid-lowering needs."

Odyssey Choice I evaluated the efficacy and safety of alirocumab in 803 patients with hypercholesterolemia at moderate to high cardiovascular (CV) risk.

It compared alirocumab 300 mg every four weeks with placebo. More than two-thirds (68 percent) of patients also received statin therapy.

Odyssey Choice II evaluated the efficacy and safety of alirocumab in 233 patients with hypercholesterolemia with high CV risk and/or a history of intolerance to two or more statins.

It compared alirocumab 150 mg every four weeks with placebo. No patients received statin therapy.

The most common adverse events in the trials (occurring in at least 5 percent of alirocumab-treated patients) were injection site reactions, headache, upper respiratory tract infection, arthralgia, nausea, sinusitis, pain in extremity, and fatigue.

Injection site reactions occurred more frequently in the alirocumab groups compared to placebo.

In both trials, alirocumab-treated patients who did not achieve their pre-specified LDL-C goals, or who did not achieve at least a 30 percent reduction in their LDL-C levels from baseline, were switched to receive alirocumab 150 mg every two weeks at 12 weeks.

"Despite current lipid-lowering therapies, many patients at high CV risk struggle to reach optimal LDL-C levels," said Dr Jay Edelberg, head of the PCSK9 development & launch unit, Sanofi. "The Odyssey clinical trial program has provided key insights and allowed us to investigate alirocumab administered every four weeks in different patient populations, including those who cannot get control of their high LDL-C because of difficulty tolerating statin therapy."