Amgen’s Monoclonal Antibody Slashes LDL-C

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Amgen announced the publication of data from the Phase 3 LAPLACE-2 (LDL-C Assessment with PCSK9 Monoclonal Antibody Inhibition Combined with Statin Therapy-2) study in the Journal of the American Medical Association (JAMA). Results from the 12-week study, which evaluated 1,896 patients with high cholesterol, showed treatment with subcutaneous evolocumab (140 mg every two weeks or 420 mg monthly) in combination with different daily doses of statin therapy significantly reduced mean low-density lipoprotein cholesterol (LDL-C) regardless of statin dose.

Evolocumab, an investigational fully human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that reduces the liver’s ability to remove LDL-C from the blood, reduced mean LDL-C by 55-76% from baseline compared to placebo and 38-47% from baseline compared to ezetimibe (p<0.001). No adverse events (AEs) occurred in ≥2% of the evolocumab combined group. The most common AEs in the evolocumab combined group were back pain, arthralgia, headache, muscle spasms and pain in extremity.

"Elevated LDL cholesterol is recognized as a major risk factor for cardiovascular disease, and although statins are effective in reducing LDL cholesterol levels, many patients may need additional LDL cholesterol lowering,” said lead investigator Jennifer Robinson, director of the Prevention Intervention Center, professor of the Departments of Epidemiology & Medicine, College of Public Health at the University of Iowa. "This is the first study to demonstrate that the addition of evolocumab results in similar percent reductions in LDL cholesterol and achieved LDL cholesterol levels regardless of stable baseline statin type, dose or intensity, across three commonly prescribed statins and a broad range of doses."

There are approximately 300 million cases of dyslipidemia in the United States, Japan and Western Europe. According to the Centers for Disease Control and Prevention, more than 71 million American adults have high LDL-C, or “bad” cholesterol, and elevated LDL-C is recognized as a major risk factor for cardiovascular disease.

"Results from the Phase 3 LAPLACE-2 study show that evolocumab provided cholesterol-lowering regardless of statin therapy and we look forward to bringing this new treatment option to patients who are taking statins and still need additional treatment options to lower their cholesterol levels,” said Sean Harper, executive vice president of Research and Development at Amgen. "These results in combination with data from other studies in our clinical trial program form the basis of our global filing plan for evolocumab and we are working closely with regulatory authorities to provide this treatment to patients with high cholesterol.”