Amgen Announces Positive Top-Line Results From 52-Week Phase 3 DESCARTES Study Of Evolocumab (AMG 145) In Patients With High Cholesterol

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Study Meets Primary Endpoint of LDL Cholesterol Reduction

THOUSAND OAKS, Calif., Dec. 19, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the Phase 3 DESCARTES (Durable Effect of PCSK9 Antibody CompARed wiTh PlacEbo Study) study evaluating the long-term 52-week safety and efficacy of evolocumab for the treatment of high cholesterol met its primary endpoint of percent reduction from baseline in low-density lipoprotein cholesterol (LDL-C) at week 52. The mean percent reduction in LDL-C, or "bad" cholesterol, was consistent with the results observed in the 52-week analysis of the Phase 2 OSLER (Open Label Study of Long TERm Evaluation Against LDL-C) study.

Evolocumab is 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.[1]

The DESCARTES study evaluated safety, tolerability and efficacy in 901 patients with high LDL-C and a range of cardiovascular risk. Background lipid-lowering therapy was optimized to one of four treatment groups (diet alone; diet plus atorvastatin 10 mg; diet plus atorvastatin 80 mg; and diet plus atorvastatin 80 mg plus ezetimibe 10 mg) for individual patients based on their LDL-C and cardiovascular risk. Patients with a fasting LDL-C ≥ 75 mg/dL were then randomized to receive monthly subcutaneous evolocumab 420 mg or placebo in combination with background lipid-lowering therapy.

Evolocumab significantly reduced LDL-C, as measured by the accepted standard, preparative ultracentrifugation, from baseline at week 52 compared to placebo. LDL-C reduction at week 12 was consistent with the long-term efficacy at week 52.

Safety was balanced across treatment groups. The most common adverse events (> 5 percent in evolocumab) were nasopharyngitis, upper respiratory tract infection, influenza and back pain.

"Data from the Phase 3 DESCARTES study of evolocumab add to the promising safety and efficacy data we recently saw in the MENDEL-2 study and 52-week Phase 2 OSLER study," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "These data contribute to the growing body of research suggesting that evolocumab may offer a new treatment option for patients with dyslipidemia."

Details of the DESCARTES study results will be submitted to a future medical conference and for publication.

According to the Centers for Disease Control and Prevention, more than 71 million American adults have high LDL-C.[2] Elevated LDL-C is recognized as a major risk factor for cardiovascular disease.[3-4]

DESCARTES Study Design

DESCARTES (Durable Effect of PCSK9 Antibody CompARed wiTh PlacEbo Study) is a Phase 3 randomized, multicenter, double-blind, placebo-controlled study designed to evaluate the long-term (52-week) safety, tolerability and efficacy of evolocumab in patients with hyperlipidemia at risk for cardiovascular disease. Background lipid-lowering therapy was optimized to one of four treatment groups (diet alone; diet plus atorvastatin 10 mg; diet plus atorvastatin 80 mg; and diet plus atorvastatin 80 mg plus ezetimibe 10 mg) for individual patients based on their LDL-C and cardiovascular risk according to the National Cholesterol Education Program Adult Treatment Panel (NCEP ATP) III risk categories. After optimization, patients were maintained on therapy for at least four weeks. A total of 901 patients with a fasting LDL-C ≥ 75 mg/dL were then randomized and received monthly subcutaneous evolocumab 420 mg or placebo in combination with background lipid-lowering therapy.

The primary endpoint was percent change from baseline in LDL-C, measured by the accepted standard, preparative ultracentrifugation, after 52 weeks of treatment. Secondary efficacy endpoints included the percent change from baseline in LDL-C and total cholesterol (TC) at week 12, and percent change from baseline at week 52 in TC, non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (ApoB), TC/HDL-C ratio, ApoB/apolipoprotein A1 (ApoA1) ratio, lipoprotein(a), triglycerides, HDL-C and very low density lipoprotein cholesterol (VLDL-C).

About PROFICIO: The Evolocumab Clinical Trial Program

PROFICIO, which stands for the Program to Reduce LDL-C and Cardiovascular Outcomes Following Inhibition of PCSK9 In Different POpulations, is a large and comprehensive clinical trial program evaluating evolocumab. Phase 3 clinical trials for evolocumab are currently underway and build upon the Phase 2 studies.

The Phase 3 program includes 13 trials, with a combined planned enrollment of more than 28,000 patients. The Phase 3 studies will evaluate evolocumab administered every two weeks and monthly in multiple patient populations, including in combination with statins in patients with hyperlipidemia (LAPLACE-2), in patients with hyperlipidemia who cannot tolerate statins (GAUSS-2), as a stand-alone treatment in patients with hyperlipidemia (MENDEL-2), and in patients whose elevated cholesterol is caused by genetic disorders called heterozygous (RUTHERFORD-2) and homozygous (TESLA and TAUSSIG) familial hypercholesterolemia.

Five studies of evolocumab will provide long-term safety and efficacy data. These include FOURIER (Further Cardiovascular OUtcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk), which will assess whether treatment with evolocumab in combination with statin therapy compared to placebo and statin therapy reduces recurrent cardiovascular events in approximately 22,500 patients with cardiovascular disease, DESCARTES (Durable Effect of PCSK9 Antibody CompARed wiTh PlacEbo Study) in patients with hyperlipidemia at risk for cardiovascular disease, and GLAGOV (GLobal Assessment of Plaque ReGression with a PCSK9 AntibOdy as Measured by IntraVascular Ultrasound), which will determine the effect of evolocumab on coronary atherosclerosis in approximately 950 patients undergoing cardiac catheterization.

Additional information about clinical trials of evolocumab can be found at www.clinicaltrials.gov.

About Evolocumab

Evolocumab is a fully human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9).[1] PCSK9 is a protein that targets LDL receptors for degradation and thereby reduces the liver's ability to remove LDL-C, or "bad" cholesterol, from the blood.[5] Evolocumab, being developed by Amgen scientists, is designed to bind to PCSK9 and inhibit PCSK9 from binding to LDL receptors on the liver surface. In the absence of PCSK9, there are more LDL receptors on the surface of the liver to remove LDL-C from the blood.[1]

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

Forward-Looking Statements

This news release contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Dec. 19, 2013 and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products are affected by the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, the discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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