Amgen Presents Long-Term Data Showing Efficacy And Safety Of Investigational Cholesterol-Lowering Medication Evolocumab Across Lipid And LDL-C Levels

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Additional Data Analysis Showed Every Two Week and Monthly Dosing Regimens of Evolocumab Were Clinically Equivalent

Amgen to Webcast Investor Call at AHA Scientific Sessions 2014

THOUSAND OAKS, Calif., Nov. 18, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced new data from three separate analyses of Phase 2 and 3 studies evaluating evolocumab, a novel investigational low-density lipoprotein cholesterol (LDL-C)-lowering medication. Data from one of the long-term pooled analyses showed that evolocumab significantly reduced lipoprotein(a) (Lp(a)) over 64 weeks. Data from a separate long-term, 52-week pooled analysis showed that adverse events (AEs) were overall balanced between patients who achieved LDL-C levels of <40 mg/dL and those who achieved LDL-C levels of ≥40 mg/dL. Another pooled analysis showed the two dosing regimens of evolocumab were clinically equivalent. These evolocumab data were included as part of the 13 presentations showcased at the American Heart Association (AHA) Scientific Sessions 2014.

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, or "bad" cholesterol, from the blood.[1]

"The long-term data analyses from our clinical development program further support that evolocumab is a potential treatment option for patients who, despite current therapies, still need help managing their condition," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The two evolocumab dosing regimens provide an option for patients who want the ability to administer evolocumab once every two weeks or monthly. We continue to work with regulatory agencies to potentially make evolocumab available to patients."

Analysis of pooled data from Phase 2, 3 and open-label extension studies of 3,278 patients with high cholesterol showed that in the year-long extension phase, treatment with subcutaneous evolocumab 140 mg every two weeks or 420 mg monthly plus standard of care (SOC) resulted in mean reductions in Lp(a) from baseline of 22 percent at 24 weeks and 29 percent at 52 weeks. The mean Lp(a) reductions showed consistency with results observed in the 12-week parent studies, indicating treatment with evolocumab resulted in significant and sustained reductions in Lp(a) over a combined period of 64 weeks (p<0.001). Lp(a) is a pro-atherogenic lipoprotein related to LDL and is associated with cardiovascular disease risk.[2]

"Historically, epidemiologic studies have shown a consistent and independent association between increased lipoprotein(a) and cardiovascular disease risk; however, current therapeutic options to reduce lipoprotein(a) are limited," said evolocumab investigator Frederick J. Raal, M.D., Ph.D., University of Witwatersrand, Johannesburg. "Results from these pooled studies show that evolocumab has significant effects across the lipid profile and was effective in reducing lipoprotein(a) over a year of treatment."

Another long-term data analysis from the Phase 2 OSLER-1 and Phase 3 DESCARTES 52-week studies compared the rate of AEs between 1,012 patients with high cholesterol who achieved low LDL-C (<40 mg/dL) and 1,187 patients with higher achieved LDL-C levels (≥40 mg/dL). Both groups had comparable rates of at least one AE (78 percent vs. 83 percent [LDL-C <40 mg/dL vs. LDL-C ≥40 mg/dL]). The overall occurrence of common AEs was balanced between LDL-C groups, and the overall event rates did not appear to be influenced by the use of intensive background statin therapy. The most common AEs across groups achieving low LDL-C and higher LDL-C, respectively, were nasopharyngitis (13.8 percent vs. 13.1 percent), upper respiratory tract infection (8.7 percent vs. 7.3 percent), influenza (5.8 percent vs. 7.2 percent), back pain (7.1 percent vs. 5.3 percent) and arthralgia (5.8 percent vs. 4.7 percent).

"The analysis from the OSLER-1 and DESCARTES studies showed that adverse events were generally balanced between patients with low and higher LDL cholesterol levels," said Michael Koren, M.D., investigator for the OSLER-1 and DESCARTES studies and chief executive officer of the Jacksonville Center for Clinical Research, Jacksonville, Fla. "We are encouraged by the promising results we continue to see with evolocumab after more than one year of treatment, and look forward to evaluating longer-term data in the future."

Additionally, a dosing regimen analysis presented at the meeting evaluated 248 patients with high cholesterol from the Phase 2 MENDEL and LAPLACE-TIMI 57 trials, and showed the greatest LDL-C reductions were comparable for evolocumab 140 mg every two weeks and 420 mg monthly dosing. Results showed reductions of 72 percent for evolocumab 140 mg every two weeks (measured one week after dosing) and 69 percent for evolocumab 420 mg monthly (measured two weeks after dosing). Similar LDL-C reductions were also observed for the mean of weeks 10 and 12 with evolocumab 140 mg every two weeks (65 percent) and 420 mg monthly (64 percent). Changes in other lipid parameters and unbound PCSK9 showed no clinically significant differences between every two-week and monthly dosing.

High cholesterol, particularly elevated LDL-C, is the most common form of dyslipidemia, which is an abnormality of cholesterol and/or fats in the blood.[3,4] Elevated LDL-C is recognized as a major risk factor for cardiovascular disease.[5,6] Familial hypercholesterolemia (FH) is an inherited condition caused by genetic mutations which lead to high levels of LDL-C at an early age,[7] and it is estimated that less than one percent of people with FH (heterozygous and homozygous forms) in the U.S. are diagnosed.[8]

Amgen will host a webcast investor call at AHA Scientific Sessions 2014 on Tuesday, Nov. 18, at 6 p.m. CST. Rob Scott, M.D., vice president of Global Development at Amgen, and Scott Wasserman, M.D., executive medical director of Global Development at Amgen, along with clinical investigators, will participate at the investor meeting to discuss Amgen's cardiovascular program, including the evolocumab data presented at the congress.

Live audio of the investor call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at

least 90 days after the event.

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.[9] 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 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 in 22 clinical trials, with a combined planned enrollment of approximately 35,000 patients.

The Phase 3 program includes 16 trials to evaluate evolocumab administered every two weeks and monthly in multiple patient populations, including in combination with statins in patients with hyperlipidemia (LAPLACE-2 and YUKAWA-2); in patients with hyperlipidemia who cannot tolerate statins (GAUSS-2 and GAUSS-3); as a stand-alone treatment in patients with hyperlipidemia (MENDEL-2); in patients whose elevated cholesterol is caused by genetic disorders called heterozygous (RUTHERFORD-2 and TAUSSIG) and homozygous (TESLA and TAUSSIG) familial hypercholesterolemia; the effects of evolocumab on lipoprotein metabolism (FLOREY); and the administration of evolocumab in statin-treated hyperlipidemic patients (THOMAS-1 and THOMAS-2).

Five ongoing studies in the evolocumab Phase 3 program 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 27,500 patients with cardiovascular disease; EBBINGHAUS (Evaluating PCSK9 Binding AntiBody Influence oN CoGnitive HeAlth in High CardiovascUlar Risk Subjects), which will evaluate the effect of evolocumab on cognitive function in a subset of patients enrolled in FOURIER; OSLER-2 (Open Label Study of Long TERm Evaluation Against LDL-C Trial-2) in patients with high cholesterol who completed any of the Phase 3 studies; 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; and TAUSSIG (Trial Assessing Long Term USe of PCSK9 Inhibition in Subjects with Genetic LDL Disorders), which will assess the long-term safety and efficacy of evolocumab on LDL-C in patients with severe familial hypercholesterolemia including patients with homozygous familial hypercholesterolemia. The DESCARTES (Durable Effect of PCSK9 Antibody CompARed wiTh PlacEbo Study) study, a long-term safety and efficacy trial in patients with hyperlipidemia at risk for cardiovascular disease, has been completed, presented and published.

About Amgen's Commitment to Cardiovascular Disease

Amgen is dedicated to addressing important scientific questions in order to advance care and improve the lives of patients with cardiovascular disease. Through its own research and development efforts and innovative partnerships, Amgen has built a robust cardiology pipeline consisting of several investigational molecules in an effort to address a number of today's important unmet patient needs, such as high cholesterol and heart failure.

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 Nov. 18, 2014, 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. Our efforts to integrate the operations of companies we have acquired may not be successful. Cost saving initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plans. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our common stock.

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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