Amgen To Discuss Details Of Repatha™ (Evolocumab) Biologics License Application For The Treatment Of High Cholesterol

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FDA Advisory Committee to Review PCSK9 Inhibitor Data

THOUSAND OAKS, Calif., June 10, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that the Company will discuss the data supporting the Repatha™ (evolocumab) Biologics License Application (BLA) for the treatment of high cholesterol with the U.S. Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC). Repatha 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 low-density lipoprotein cholesterol (LDL-C), or "bad" cholesterol, from the blood.[1]

At today's FDA advisory committee meeting, Amgen will present Repatha clinical trial data from approximately 6,800 patients, including more than 4,500 patients with high cholesterol in 10 Phase 3 trials. The Phase 3 studies evaluated the efficacy and safety of Repatha in patients with elevated cholesterol, including patients on statins with or without other lipid-lowering therapies; patients who cannot tolerate statins; patients with heterozygous familial hypercholesterolemia (HeFH) and patients with homozygous familial hypercholesterolemia (HoFH), a rare and serious genetic disorder.[2]

"We look forward to discussing the efficacy and safety data from our clinical program with the FDA advisory committee as there remains a significant unmet medical need for patients who, despite currently available therapies, are unable to control their high cholesterol," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "If approved, Repatha would provide patients and physicians with an important new treatment option for managing high cholesterol."

The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of Aug. 27, 2015, for the Repatha BLA.

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] Nearly one in three Americans have elevated LDL-C,[5] which is recognized as a major risk factor for cardiovascular disease.[6,7] Familial hypercholesterolemia (FH) is an inherited condition caused by genetic mutations which lead to high levels of LDL-C at an early age,[2] and it is estimated that less than one percent of people with FH (heterozygous and homozygous forms) in the U.S. are diagnosed.[8]

PROFICIO Clinical Program Results

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 Repatha. PROFICIO includes 22 clinical trials, with a combined planned enrollment of approximately 35,000 patients.

In data from the clinical program to date, Repatha has demonstrated consistent, significant and durable reduction in LDL-C levels with favorable effects on other lipid parameters in approximately 6,000 patients with primary hyperlipidemia and mixed dyslipidemia.[9] In these studies, Repatha reduced LDL-C by approximately 55 percent to 75 percent compared with placebo[10-13] and by approximately 35 percent to 45 percent compared with ezetimibe.[10,11,13] In patients with HoFH, Repatha reduced LDL-C by approximately 30 percent compared with placebo.[14] Reduction of LDL-C was maintained with long-term treatment.[15]

The adverse event profile for Repatha was similar overall to that of the control groups.[10-16] The most common adverse events that occurred in greater than or equal to 2 percent of the Repatha group, and more frequently than in the control group, were nasopharyngitis (5.9 percent Repatha; 4.8 percent any control), upper respiratory tract infection (3.2 percent Repatha; 2.7 percent any control), back pain (3.0 percent Repatha; 2.7 percent any control), arthralgia (2.3 percent Repatha; 2.2 percent any control), influenza (2.1 percent Repatha; 2.0 percent any control) and nausea (2.1 percent Repatha; 1.8 percent any control).

About Repatha™ (evolocumab)

Repatha™ (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.[17] Repatha, 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]

The FDA has provisionally approved the use of the trade name Repatha.

About Amgen Cardiovascular

Building on more than three decades of experience in developing biotechnology medicines for patients with serious illnesses, Amgen is dedicated to addressing important scientific questions to advance care and improve the lives of patients with cardiovascular disease, the leading cause of morbidity and mortality worldwide.[18] Amgen's research into cardiovascular disease, and potential treatment options, is part of a growing competency at Amgen that utilizes human genetics to identify and validate certain drug targets. Through its own research and development efforts, as well as partnerships, Amgen is building a robust cardiovascular 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 one of the world's leading independent biotechnology companies, 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 June 10, 2015, 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. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plan. 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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