Amgen Submits Application For Investigational LDL Cholesterol-Lowering Medication Repatha™ (evolocumab) In Japan

March 20, 2015

Submission of Application in Japan Marks an Important Milestone in Strategic Partnership With Amgen Astellas BioPharma

THOUSAND OAKS, Calif., March 20, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that an application seeking marketing approval of Repatha™ (evolocumab) for the treatment of high cholesterol has been submitted for review to the Ministry of Health, Labour and Welfare in Japan. Repatha is being developed in Japan by Amgen Astellas BioPharma K.K., a joint venture between Amgen and Astellas Pharma Inc., a pharmaceutical company headquartered in Tokyo.

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] In Japan, LDL-C levels are not adequately controlled for many patients taking statins, nearly half of whom have not reached their LDL-C goal.[2,3]

"Submitting Repatha for marketing approval in Japan is an important milestone in our strategic partnership alliance with Astellas Pharma as we look forward to accomplishing our common goal of addressing the critical needs of patients with high cholesterol," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to working with regulatory authorities in Japan to provide a new treatment option for patients whose cholesterol is uncontrolled with currently available therapies."

The Japanese New Drug Application for marketing approval for Repatha contains data from approximately 7,200 patients with high cholesterol in 11 Phase 3 trials, including Japanese patients from studies conducted in Japan. Overall, the Phase 3 studies evaluated the safety and efficacy of Repatha in patients with elevated cholesterol 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.[4]

In the U.S., Amgen submitted a Biologics License Application for Repatha for the treatment of high cholesterol to the Food and Drug Administration (FDA) in August 2014. The FDA's Prescription Drug User Fee Act target action date is Aug. 27, 2015. In the European Union, Amgen submitted a Marketing Authorization Application to the European Medicines Agency via the centralized procedure for Repatha for the treatment of high cholesterol in September 2014.

High cholesterol is the most common form of dyslipidemia, which is an abnormality of cholesterol and/or fats in the blood.[5,6] There are approximately 300 million cases of dyslipidemia in the U.S., Japan and Western Europe.[7]

Familial hypercholesterolemia (FH) is an inherited condition caused by genetic mutations which lead to high levels of LDL-C at an early age,[4] and it is estimated that less than one percent of people with FH (heterozygous and homozygous forms) in Japan are diagnosed.[8] Patients can have either one of two types of FH.[4] Heterozygous FH is the more common type of FH and in Japan, occurs in approximately one in 900 individuals.[8,9] It can cause LDL-C levels twice as high as normal (e.g., >190 mg/dL).[10] Individuals with HeFH have one altered copy of a cholesterol-regulating gene.[10] Homozygous FH is the rare, more severe form, occurring in approximately one in a million individuals.[11] It can cause LDL-C levels more than six times as high as normal (e.g., 500-1,000 mg/dL).[12,13] An individual with HoFH has two altered copies of cholesterol-regulating genes (one from each parent).[4]

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.[14] 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 trademark Repatha has been filed and is registered in Japan. The FDA has provisionally approved the trade name Repatha.

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 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 March 20, 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 payers, 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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