FDA Grants Amgen Priority Review Designation For Ivabradine For The Treatment Of Chronic Heart Failure

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THOUSAND OAKS, Calif., Aug. 27, 2014 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced the U.S. Food and Drug Administration (FDA) has granted priority review designation for ivabradine for the treatment of chronic heart failure (HF). Ivabradine is an oral drug that inhibits the I_f current ("funny" current) in the sinoatrial node, the body's cardiac pacemaker.[1] Ivabradine works to slow the heart rate without negative effects on myocardial contractility or ventricular repolarization.[1] Heart failure is a common condition that affects approximately 26 million worldwide, including approximately 5.1 million people in the U.S.[2,3]

"The priority review designation by the FDA is evidence that chronic heart failure is a serious condition, which leads to high rates of rehospitalization and poor prognosis despite available treatments. If approved, ivabradine would potentially provide a significant improvement, on top of standard-of-care therapies, for this grievous condition," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are excited about the opportunity to bring this important therapeutic option to certain patients with chronic heart failure in the U.S."

The New Drug Application (NDA) is based on global clinical trial data from the Phase 3 SHIFT (Systolic Heart failure treatment with the I_f inhibitor ivabradine Trial) study, a large, multi-center, randomized, double-blind, placebo-controlled, outcomes trial. The pivotal SHIFT study compared ivabradine to placebo on top of standard-of-care therapies, including beta-blockers, in more than 6,500 patients in sinus rhythm with reduced left ventricular function and heart rate ≥70 beats per minute (bpm).

Priority review designation is assigned to applications for drugs that treat serious conditions and would, if approved, provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies. A priority review designation will set a goal date for taking action on an application within six months of receipt.[4]

In addition, in April 2014, the FDA granted fast track designation for ivabradine for patients with chronic HF. A fast track designation is a process intended to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Products that have been designated as fast track can submit portions of a marketing application before submitting the complete application, known as rolling review.[5]

Heart failure is the leading cause of rehospitalization in Medicare beneficiaries over age 55,[6] and approximately 50 percent of people diagnosed with HF in the U.S. die within five years of diagnosis.[3] Projections show that by 2030, the prevalence of HF will increase 25 percent from 2013 estimates.[3] Despite broad use of standard treatments, the prognosis for HF is poor.[7]

About Ivabradine

Ivabradine is an investigational oral drug that inhibits the I_f current ("funny" current) in the sinoatrial node, the body's cardiac pacemaker.[1] Ivabradine works to slow the heart rate without negative effects on myocardial contractility or ventricular repolarization.[1] Developed by Les Laboratoires Servier, ivabradine was approved by the European Medicines Agency (EMA) as PROCORALAN® in 2005 for the symptomatic treatment of stable angina and in 2012 for chronic heart failure (HF) in patients with elevated heart rates. Through a collaboration with Servier, Amgen has rights to commercialize ivabradine in the U.S.

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 Aug. 27, 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 Amgen Inc. and its subsidiaries (which are collectively referred to as we, or us) 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 and our partners 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 product liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. 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 (including products of our wholly-owned subsidiaries) 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 and our partners routinely obtain patents for products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our or our partners' 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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