Amgen Receives Positive CHMP Opinion For Parsabiv™ (Etelcalcetide) For The Treatment Of Secondary Hyperparathyroidism In Adult Patients With Chronic Kidney Disease On Hemodialysis

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Novel Treatment Administered Intravenously Would put Delivery of Important Therapy in the Hands of the Healthcare Provider

THOUSAND OAKS, Calif., Sept. 16, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for the Marketing Authorization of Parsabiv™ (etelcalcetide), recommending approval for the treatment of secondary hyperparathyroidism (sHPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. If approved, Parsabiv will be the first calcimimetic agent that can be administered intravenously by a healthcare provider three times a week at the end of a hemodialysis session.

"We are pleased to receive a positive CHMP opinion for Parsabiv, which has demonstrated strong efficacy in clinical trials and could help fill an unmet need in the delivery of this important therapy," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Secondary hyperparathyroidism is a disease that affects many patients with advanced chronic kidney disease, and we look forward to continuing to work with regulatory authorities to provide these patients with a novel therapy and advance the management of this complex disease."

The Marketing Authorization Application (MAA) submission for Parsabiv included data from three Phase 3 studies, all of which met their primary endpoints, including two pooled placebo-controlled trials in more than 1,000 patients and a head-to-head study evaluating Parsabiv compared with cinacalcet.

The CHMP positive opinion will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). If approved, a centralized marketing authorization with unified labeling will be granted in the 28 countries that are members of the EU. Norway, Iceland and Liechtenstein, as members of the European Economic Area (EEA), will take corresponding decisions on the basis of the decision of the EC.

About Secondary Hyperparathyroidism (sHPT)

sHPT is a chronic and serious condition which affects many of the approximately two million people throughout the world who are receiving dialysis.[1-4] In Europe, the prevalence of sHPT within dialysis populations ranges from 30 to 49 percent.[5] Approximately 88 percent of dialysis patients and 79 percent of patients on hemodialysis will develop sHPT.[6] sHPT refers to the excessive secretion of parathyroid hormone (PTH) by the parathyroid glands in response to decreased renal function and impaired mineral metabolism.[1] The elevated levels of PTH can lead to an increase in the release of calcium and phosphorus from the bones.[7] sHPT is often initially silent and asymptomatic. As a result, sHPT is frequently underdiagnosed and undertreated.[8]

About Parsabiv™ (etelcalcetide)

Parsabiv is a novel calcimimetic agent in clinical development for the treatment of sHPT in adult CKD patients on hemodialysis that is administered intravenously at the end of the hemodialysis session. A calcimimetic is a drug that mimics the action of calcium by activating the calcium-sensing receptors on the parathyroid gland. Parsabiv binds to and activates the calcium-sensing receptor on the parathyroid gland, thereby decreasing PTH levels.

About Mimpara® (cinacalcet)

Mimpara® (cinacalcet) is the first oral calcimimetic agent approved by the EMA for the treatment of sHPT in patients with CKD on dialysis. The therapy is also approved in the EU for the treatment of hypercalcemia in patients with parathyroid carcinoma and hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated. Mimpara binds to the calcium-sensing receptor, resulting in a drop in PTH levels by inhibiting PTH synthesis and secretion. In addition, the reductions in PTH lower serum calcium and phosphorus levels.

Important Safety Information

Mimpara lowers serum calcium; therefore, it is important that patients are carefully monitored for the occurrence of hypocalcaemia. Mimpara should not be initiated if serum calcium (corrected for albumin) is less than the lower limit of the normal range. The threshold for seizures is lowered by significant reductions in serum calcium levels. In the treatment of secondary hyperparathyroidism the most commonly reported adverse reactions in clinical trials were nausea and vomiting.

To see the full Mimpara Safety Information, visit www.ema.europa.eu/ema/

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 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 the current expectations and beliefs of Amgen. 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 reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. 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 results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and 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. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. 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. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. 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. Further, 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, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our 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 or the European Medicines Agency, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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