Amgen Announces Top-Line Results Of Phase 3 Sensipar®/Mimpara® EVOLVE(TM) Trial

June 8, 2012

THOUSAND OAKS, Calif., June 8, 2012 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced top-line results of the Phase 3 EVOLVE(TM) (EValuation Of Cinacalcet HCl Therapy to Lower CardioVascular Events) trial, which evaluated Sensipar®/Mimpara® (cinacalcet) for the reduction of the risk of mortality and cardiovascular (CV) events among 3,883 patients with secondary hyperparathyroidism (HPT) and chronic kidney disease (CKD) receiving dialysis. The primary endpoint of the study was time to the composite event comprising all-cause mortality or first non-fatal cardiovascular event, including myocardial infarction, hospitalization for unstable angina, heart failure or peripheral vascular event. Although patients in the Sensipar/Mimpara arm experienced numerically fewer composite primary events, the results were not statistically significant, and the trial did not meet its primary endpoint in the intent-to-treat analysis.

"Amgen embarked on the EVOLVE trial to understand whether treating secondary HPT with Sensipar/Mimpara could positively impact the high rates of mortality and cardiovascular events among patients with CKD receiving dialysis," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We thank the patients, caregivers and investigators for their participation and engagement in this landmark trial. EVOLVE will provide the nephrology community with important information."

The most frequently reported adverse events in the Sensipar/Mimpara arm of the trial were consistent with the known safety profile of this therapy and included nausea, vomiting and hypocalcemia.

Detailed efficacy and safety analyses from this landmark study are ongoing and will be submitted for presentation at a major medical meeting later this year.

Sensipar/Mimpara is an oral calcimimetic agent approved for the treatment of secondary HPT in patients with CKD receiving dialysis.

EVOLVE Trial Design

EVOLVE was an international, randomized, double-blind, placebo-controlled Phase 3 study of 3,883 patients with secondary HPT and CKD receiving dialysis. The trial, the largest of its kind in patients with CKD receiving dialysis, was designed to determine if treatment with Sensipar/Mimpara, compared to placebo, decreases the risk of all-cause mortality and CV morbidity. The trial consisted of a 30-day screening phase, a titration phase with visits every 2 weeks, and a follow-up phase with visits every 8 weeks. Following the screening phase, patients were randomized to the Sensipar/Mimpara or placebo groups. Possible sequential doses of Sensipar/Mimpara or placebo included 30, 60, 90, 120, and 180 mg. Flexible use of traditional therapies, such as vitamin D derivatives and phosphate binders, were permitted in both groups.

About Secondary Hyperparathyroidism

Secondary hyperparathyroidism (HPT) is a common and serious condition that is often progressive among patients with CKD and it affects many of the approximately two million people throughout the world who are receiving dialysis. The disorder develops early as an adaptive response to declining kidney function when the parathyroid glands (four small glands in the neck) increase the production of parathyroid hormone (PTH) in an effort to maintain normal levels of calcium and phosphorus. Ultimately, excess PTH production proves inadequate for maintaining normal serum calcium and phosphorous levels. When kidney disease progresses to the point where dialysis is needed to sustain life, secondary HPT manifests as elevated PTH, calcium and phosphorus levels that, in turn, can lead to significant clinical consequences, including bone loss, skeletal fracture, and soft-tissue calcification. Although many patients with secondary HPT are not overtly symptomatic, bone pain, particularly when standing or when walking, achy and stiff joints, muscle weakness, and complaints of dry, itchy skin are common. Advanced disease is marked by very large parathyroid glands that may need to be removed by surgery.

About Sensipar/Mimpara (cinacalcet)

Cinacalcet is approved in more than 50 countries and marketed as Sensipar in the United States (U.S.), Canada, Australia and New Zealand and as Mimpara in the European Union and other countries. Sensipar/Mimpara is the first oral calcimimetic agent approved for the treatment of secondary HPT in CKD patients receiving dialysis. The therapy is also approved by the U.S. Food and Drug Administration, European Medicines Agency and Health Canada for hypercalcemia in patients with parathyroid carcinoma and severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy. Sensipar/Mimpara binds to the calcium-sensing receptor, which causes the receptor to become more sensitive to extracellular calcium ions. This results in a drop in PTH levels by inhibiting PTH synthesis and secretion. In addition, the reductions in PTH lower serum calcium and phosphorus levels.

Secondary HPT Indication
Sensipar is indicated for the treatment of secondary HPT in patients with CKD on dialysis.

Primary HPT Indication
Sensipar is indicated for the treatment of severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

Important Safety Information

Sensipar lowers serum calcium; therefore, it is important that patients are carefully monitored for the occurrence of hypocalcemia. Sensipar should not be initiated if serum calcium is less than the lower limit of the normal range. Significant reductions in calcium may lower the threshold for seizures. In the treatment of secondary hyperparathyroidism the most commonly reported side effects in clinical trials were nausea, vomiting, and diarrhea. In the treatment of primary hyperthyroidism, the most commonly reported side effects in clinical trials were nausea, vomiting, and paresthesia.

To see the full Sensipar Safety Information, visit http://pi.amgen.com/united_states/sensipar/sensipar_pi_hcp_english.pdf.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and vital medicines, visit http://www.amgen.com/. Follow us on http://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 most recent 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 8, 2012 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.

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. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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