Amgen Announces Positive Results From Head-To-Head Study Comparing The Efficacy And Safety Of AMG 416 With Cinacalcet In Patients With Secondary Hyperparathyroidism Receiving Hemodialysis

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Third Phase 3 Study Met Non-Inferiority and Superiority Endpoints in the Reduction of Parathyroid Hormone

THOUSAND OAKS, Calif., Feb. 25, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced results from the head-to-head Phase 3 study comparing AMG 416 with cinacalcet for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) receiving hemodialysis. The study met the primary endpoint of non-inferiority of AMG 416 compared to cinacalcet, measured as the achievement of a greater than 30 percent reduction from baseline in mean pre-dialysis serum intact parathyroid hormone (PTH) levels during the Efficacy Assessment Phase (EAP), defined as the period between weeks 20 and 27.

Further, AMG 416 was statistically significantly superior to cinacalcet in the secondary endpoints of the proportion of patients achieving greater than 50 percent (52.4 percent versus 40.2 percent) and greater than 30 percent (68.2 percent versus 57.7 percent) PTH reduction from baseline during the EAP. There was no difference between the treatment arms in the mean number of days of vomiting or nausea per week in the first eight weeks, another secondary endpoint.

"These findings, combined with results from two positive placebo-controlled studies of more than 1,000 patients, add to the growing body of evidence that reinforce the promise of AMG 416 for hemodialysis patients with secondary hyperparathyroidism," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The management of this disease in patients with chronic kidney disease is a complex process, and at Amgen, we are committed to building upon our leadership in nephrology to provide patients with an innovative therapy that can be administered intravenously along with hemodialysis."

Treatment-emergent adverse events (TEAEs) were reported in 92.9 and 90.0 percent of patients who received AMG 416 and cinacalcet, respectively. TEAEs that were reported in greater than 10 percent of patients in either arm included (AMG 416 versus cinacalcet, respectively): blood calcium decreased (68.9 and 59.8 percent), nausea (18.3 and 22.6 percent), vomiting (13.3 and 13.8 percent) and diarrhea (6.2 and 10.3 percent). TEAEs of hypocalcemia (symptomatic) were reported in 5.0 percent of patients who received AMG 416 versus 2.3 percent in the cinacalcet group. Treatment-emergent events related to cardiac failure were reported in 3.0 percent of patients who received AMG 416 versus 0.6 percent in the cinacalcet group. Serious adverse events were reported in 25.1 and 27.3 percent of patients who received AMG 416 and cinacalcet, respectively. Fatal adverse events were reported in 2.7 percent for the AMG 416 arm and 1.8 percent for the cinacalcet arm.

Study Design
This was a randomized, active-controlled, double-blind, double-dummy study (study number 20120360) over 26 weeks that compared the efficacy and safety of AMG 416 with cinacalcet for the treatment of SHPT in 683 patients with CKD receiving hemodialysis.

Patients randomized to treatment with AMG 416 received intravenous (IV) doses of AMG 416 three times per week at the end of each dialysis session and daily oral doses of placebo tablets. Subjects randomized to treatment with cinacalcet received daily oral doses of cinacalcet tablets and IV doses of placebo three times per week at the end of each dialysis session. Patients also received standard of care, which could include calcium supplements, vitamin D sterols and phosphate binders, if prescribed by the individual physician.

The primary endpoint was the proportion of patients with greater than 30 percent reduction from baseline in PTH levels during weeks 20 and 27, with the objective of demonstrating non-inferiority of AMG 416 to cinacalcet.

Key and other secondary endpoints included the achievement of a greater than 50 percent reduction from baseline in mean pre-dialysis serum intact PTH during the EAP, achievement of a greater than 30 percent reduction from baseline in mean pre-dialysis serum intact PTH during the EAP, and the mean number of days of vomiting or nausea per week in the first eight weeks. Nausea or vomiting were collected by the Nausea/Vomiting Symptom Assessment (NVSA) patient assessment daily questionnaires.

About Secondary Hyperparathyroidism
SHPT 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 PTH in an effort to maintain normal levels of calcium and phosphorus. Ultimately, excess PTH production proves inadequate for maintaining normal serum calcium and phosphorus levels. When kidney disease progresses to the point where dialysis is needed to sustain life, SHPT manifests as abnormal PTH, calcium and phosphorus levels that, in turn, can lead to significant clinical consequences.

About AMG 416
AMG 416 is a novel calcimimetic agent in Phase 3 clinical development for the treatment of SHPT that is administered intravenously in patients with CKD who are receiving hemodialysis. AMG 416 binds to and activates the calcium-sensing receptor on the parathyroid gland, thereby decreasing serum intact PTH levels.

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 the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen or us) 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 Inc., including Amgen Inc.'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 Inc.'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 Feb. 25, 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 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 or our partners' 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. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our restructuring plan. 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 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, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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