Amgen Announces Positive Phase 3 Results for AMG 416 for the Treatment of Secondary Hyperparathyroidism in Patients with Chronic Kidney Disease Receiving Hemodialysis

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Analysis Shows Study Met Primary and All Secondary Endpoints
AMG 416 is a Novel Calcimimetic Administered Intravenously

THOUSAND OAKS, Calif., July 17, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that a Phase 3 study evaluating AMG 416 (formerly known as velcalcetide) for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD), receiving hemodialysis, met its primary and all secondary endpoints. The primary endpoint was the proportion of patients with > 30 percent reduction from baseline in parathyroid hormone (PTH) levels during an Efficacy Assessment Phase (EAP) defined as the period between weeks 20 and 27. Amgen obtained AMG 416 as part of the acquisition of KAI Pharmaceuticals, Inc. in July 2012 and these are the first results to be reported from the Phase 3 program.

In the AMG 416 group, 75.3 percent of patients achieved a > 30 percent reduction from baseline in PTH compared with 9.6 percent in the placebo arm, a statistically significant result. Secondary endpoints included the percent change from baseline during the EAP in serum phosphorus (P) concentration (mean changes of -9.63 and -1.60 percent among patients in the AMG 416 and placebo arms, respectively) and corrected calcium (cCa) concentration (mean changes of -6.69 and 0.58 percent among patients in the AMG 416 and placebo arms, respectively). Both of these secondary endpoint results were statistically significant.

"Secondary hyperparathyroidism can be a challenging disease to manage and control. There is an important role for an effective calcimimetic that can be administered intravenously with hemodialysis to help treat this disease," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are encouraged by the results of this study and look forward to sharing results from a second placebo-controlled study later this year, and a head-to-head study evaluating AMG 416 compared to cinacalcet next year."

Treatment-emergent adverse events (TEAEs) were reported in 91.7 and 81.1 percent of patients who received AMG 416 and placebo, respectively. TEAEs that were reported in > 10 percent of patients who received AMG 416 included (AMG 416 vs placebo, respectively): blood calcium decreased (66.7 and 12.0 percent), diarrhea (14.3 and 10.0 percent), and muscle spasms (11.1 and 6.2 percent). Serious adverse events (SAEs) were reported in 24.6 and 27.4 percent of patients who received AMG 416 and placebo, respectively. TEAEs of nausea were reported in 9.1 and 7.3 percent of patients who received AMG 416 and placebo, respectively. TEAEs of vomiting were reported in 7.5 and 3.1 percent of patients treated with AMG 416 and placebo, respectively. TEAEs of hypocalcemia (symptomatic) were reported in 6.7 percent of patients who received AMG 416 versus none in the placebo group.

Study Design

This was a 26-week, randomized, double-blind, placebo-controlled study (study number 20120230) that evaluated the efficacy and safety of AMG 416 for the treatment of SHPT in 515 patients with CKD receiving hemodialysis. Patients received AMG 416 or placebo three times per week by intravenous injection with each hemodialysis treatment. Doses ranged from a minimum of 2.5 mg to a maximum of 15 mg. Patients also received standard of care which could include calcium supplements, vitamin D sterols and phosphate binders, if prescribed by the individual physician.

Secondary endpoints included the proportion of patients with PTH ≤ 300 pg/mL during the EAP and the percent change from baseline during the EAP in values for PTH, serum cCa, corrected calcium-phosphorus product (cCa x P) and P.

About Secondary Hyperparathyroidism

Secondary 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 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, 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 causing decreases in PTH.

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 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 July 17, 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 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 Amgen and its partners routinely obtain patents for their 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.

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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