Amgen Presents Pooled Phase 3 AMG 416 Data For The Treatment Of Secondary Hyperparathyroidism In Patients With Chronic Kidney Disease

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Pivotal Phase 3 Data Highlight Safety, Efficacy of AMG 416
Significant Reductions in Parathyroid Hormone Concentrations Observed in Hemodialysis Patients
Global Regulatory Filings Planned for 2015

THOUSAND OAKS, Calif., May 29, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced pooled data from two pivotal Phase 3, global, randomized, placebo-controlled trials evaluating AMG 416, a novel calcimimetic, for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) receiving hemodialysis. Both studies met the primary endpoint, demonstrating that a greater proportion of patients in the AMG 416 groups achieved a greater than 30 percent reduction in parathyroid hormone (PTH) during the Efficacy Assessment Phase compared with placebo. The data were presented today at the 52nd ERA-EDTA Congress in London.

"Secondary hyperparathyroidism is a complex and challenging condition that can be difficult to manage, as it may require patients to take demanding drug regimens multiple times a day," said John Cunningham, lead author of the studies, professor of Nephrology at the University College London Medical School and consultant physician at The Royal Free Hospital, London. "Providing patients with chronic kidney disease on hemodialysis with a calcimimetic that can be administered intravenously on the same schedule as dialysis has the potential to fulfill an unmet need in this patient population."

AMG 416 is a novel calcimimetic agent in clinical development for the treatment of SHPT in patients with CKD who are receiving hemodialysis. In the registrational programs, AMG 416 is administered intravenously at the end of dialysis. AMG 416 acts by binding to and activating the calcium-sensing receptor on the parathyroid gland, thereby causing decreases in PTH. Sustained elevations in PTH are known to lead to significant clinical consequences for patients with CKD.

In the two Phase 3 placebo-controlled studies, an aggregate of 1,023 patients with moderate-to-severe SHPT (PTH greater than 400 pg/mL) on hemodialysis were randomized to receive intravenous AMG 416 or placebo three times a week. The primary endpoint of both studies was the proportion of patients achieving greater than 30 percent reduction in PTH during the Efficacy Assessment Phase, defined as weeks 20 through 27. Secondary endpoints included the proportion of patients with PTH less than or equal to 300 pg/mL, and percent reductions in PTH, albumin adjusted calcium (cCa), phosphate (P) and cCa x P. In the AMG 416 group, 74.7 percent of patients achieved a greater than 30 percent reduction from baseline in PTH compared with 8.9 percent in the placebo arm.

Furthermore, a statistically significant proportion of patients (51.5 percent) randomized to receive AMG 416 achieved PTH less than or equal to 300 pg/mL, compared with 5.9 percent in the placebo-controlled group, despite similar baseline mean PTH values of 724 pg/mL and 716 pg/mL, respectively. Significant reductions in phosphate as well as fibroblast growth factor 23 (FGF23) were also observed, with two-thirds of AMG 416-treated patients experiencing a greater than 30 percent reduction in FGF23 concentrations compared with 30 percent of placebo-treated patients.

Reductions in serum calcium were observed and symptomatic hypocalcemia occurred more frequently in patients treated with AMG 416 compared to placebo (7.0 percent versus 0.2 percent, respectively). Additional adverse events included muscle spasms and gastrointestinal symptoms (e.g. nausea and vomiting), and they were reported more frequently with AMG 416 compared with placebo. Rates of death, adjudicated major non-fatal cardiovascular events and seizures were similar in both groups.

"These positive pivotal data further underscore the potential of AMG 416 in reducing parathyroid hormone concentrations, and ultimately, in helping treat patients impacted by this challenging disease," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are excited to build on our leadership in nephrology and help provide patients with chronic kidney disease on hemodialysis with a new therapeutic option."

Study Design
There were two 26-week, randomized, double-blind, placebo-controlled studies (study numbers 20120229 and 20120230) that evaluated the efficacy and safety of AMG 416 for the treatment of SHPT in a total of 1,023 patients with CKD receiving hemodialysis. Patients received AMG 416 or placebo three times per week by intravenous injection at the end of 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.

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. When kidney disease progresses to the point where dialysis is needed to sustain life, SHPT usually manifests as elevated PTH and an abnormal calcium and phosphorus balance that 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 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 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 May 29, 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 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. 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 recently announced restructuring plan. 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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