



## FDA Accepts Amgen's New Drug Application For Novel Intravenous Calcimimetic Etelcalcetide

November 6, 2015

THOUSAND OAKS, Calif., Nov. 6, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review Amgen's New Drug Application (NDA) for etelcalcetide (formerly AMG 416) for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) on hemodialysis. If approved, etelcalcetide will be the first calcimimetic agent that can be administered intravenously.

"We're pleased that the FDA has accepted our submission and look forward to advancing our conversations toward a potential approval in the U.S.," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Etelcalcetide has a novel method of administration that has the potential to help fill an unmet need for the many patients impacted by secondary hyperparathyroidism."

Etelcalcetide is a novel calcimimetic agent that suppresses the secretion of parathyroid hormone and is in clinical development for the treatment of SHPT in patients with CKD on hemodialysis. Etelcalcetide is administered intravenously three times per week at the end of each dialysis session. It acts by binding to and activating the calcium-sensing receptor on the parathyroid gland, thereby causing decreases in parathyroid hormone (PTH). Sustained elevations in PTH are known to be associated with significant clinical consequences for patients with CKD.

The NDA, submitted on Aug. 24, 2015, is based on data from three Phase 3 studies, including two pooled placebo-controlled trials in more than 1,000 patients and a head-to-head study evaluating etelcalcetide compared with cinacalcet.

The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of Aug. 24, 2016, for the etelcalcetide application.

### 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, including 450,000 people in the U.S. The disorder develops early in the course of CKD and usually manifests as increased levels of PTH as a result of increased production from the parathyroid glands (four small glands in the neck). Patients with end stage renal disease who require maintenance dialysis often have substantial elevations of PTH that are commonly associated with abnormal calcium and phosphorus levels and an increased risk of significant clinical consequences.

### About Etelcalcetide (formerly AMG 416)

Etelcalcetide is a novel calcimimetic agent in clinical development for the treatment of SHPT in CKD patients on hemodialysis that is administered intravenously at the end of the dialysis session. Etelcalcetide binds to and activates the calcium-sensing receptor on the parathyroid gland, thereby decreasing PTH levels.

### About Sensipar® (cinacalcet)

Sensipar® (cinacalcet) is the first oral calcimimetic agent approved by the FDA for the treatment of SHPT in adult patients with CKD on dialysis. Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia. The therapy is also approved in the U.S. for treatment of hypercalcemia in adult patients with parathyroid carcinoma and hypercalcemia in adult patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy. Sensipar 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

Sensipar® (cinacalcet) treatment initiation is contraindicated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL).

Sensipar® lowers serum calcium; therefore, it is important that patients are carefully monitored for the occurrence of hypocalcemia. Life threatening events and fatal outcomes associated with hypocalcemia have been reported in patients treated with Sensipar®, including pediatric patients. Decreases in serum calcium can prolong the QT interval, potentially resulting in ventricular arrhythmia. Cases of QT prolongation and ventricular arrhythmia secondary to hypocalcemia have been reported in patients treated with Sensipar®.

Significant reductions in calcium may lower the threshold for seizures. Patients, particularly those with a history of seizure disorder, should be carefully monitored for the occurrence of low serum calcium or symptoms of hypocalcemia.

In Sensipar® postmarketing use, isolated, idiosyncratic cases of hypotension, worsening heart failure, and/or arrhythmia were reported in patients with impaired cardiac function. The causal relationship to Sensipar® therapy could not be completely excluded and may be mediated by reductions in serum calcium levels.

Adynamic bone disease may develop if intact parathyroid hormone (iPTH) levels are suppressed below 100 pg/mL. Patients with moderate to severe hepatic impairment should be monitored throughout treatment with Sensipar®, as cinacalcet exposure assessed by area under the curve (AUC) was higher than in patients with normal hepatic function. Patients with secondary HPT: Serum calcium and serum phosphorus should be measured within 1 week and PTH should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar®. Once the maintenance dose has been established, serum calcium and serum phosphorus should be measured approximately monthly, and PTH every 1 to 3 months. Patients with primary HPT or parathyroid carcinoma: Serum calcium should be measured within 1 week after initiation or dose adjustment of Sensipar®. Once maintenance dose levels have been established, serum calcium should be measured every 2 months. In clinical trials of patients with secondary HPT comparing Sensipar® to placebo, the most commonly reported side effects were nausea (31 percent vs. 19 percent), vomiting (27 percent vs. 15 percent), and diarrhea (21 percent vs. 20 percent). In clinical trials of patients with primary HPT and parathyroid carcinoma treated with Sensipar®, the most commonly reported side effects were nausea (63 percent), vomiting (46 percent), and paresthesia (20 percent).

Please see [Full Prescribing Information](#).

## 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](http://www.amgen.com) and follow us on [www.twitter.com/amgen](http://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 Nov. 6, 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 ongoing 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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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/fda-accepts-amgens-new-drug-application-for-novel-intravenous-calcimimetic-etelcalcetide-300174208.html>

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