FDA Approves Innovative, First-In-Class Treatment for a Serious Complication of Chronic Kidney Disease

March 9, 2004

Amgen Introduces Sensipar(TM) Approved to Treat Secondary Hyperparathyroidism in Dialysis Patients

THOUSAND OAKS, Calif., March 8 -- Amgen Inc. (Nasdaq: AMGN), the world's largest biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) approved Sensipar (cinacalcet HCl) following a priority review. Sensipar, an innovative, first-in-class oral calcimimetic, is indicated for the treatment of secondary hyperparathyroidism (secondary HPT) in chronic kidney disease (CKD) patients on dialysis and the treatment of elevated calcium levels (hypercalcemia) in patients with parathyroid carcinoma; and has been shown to be safe and effective.

Nearly all of the more than 300,000 dialysis patients in the U.S. suffer from secondary HPT. The disease can develop early during the course of CKD and continues to progress as kidney function declines. Untreated secondary HPT is characterized by abnormal calcium and phosphorus levels and is associated with serious consequences, including cardiovascular morbidity.

Sensipar meets a significant medical need in patients with secondary HPT. "It is the only available therapy that allows practitioners to reduce parathyroid hormone (PTH) while lowering calcium-phosphorus product, which is consistent with the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (K/DOQI) clinical practice guidelines for bone metabolism and disease in chronic kidney disease," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development at Amgen.

The NKF's K/DOQI clinical practice guidelines are a response to the strong correlation between these biochemical parameters and morbidity and mortality in the CKD population.

"Amgen is very proud to offer this innovative, safe and effective medicine to patients and physicians. This major milestone demonstrates Amgen's prowess to bring efficacious and innovative medicines to market quickly and efficiently," said Seidenberg.

Secondary Hyperparathyroidism

Secondary HPT is characterized by elevations in PTH, calcium and phosphorus levels. If left untreated, patients with secondary HPT develop bone disease, bone pain and fractures, vascular and soft tissue calcifications, which are frequently associated with an increased risk of hospitalization and death.

Prior to the approval of Sensipar, the only available medical treatments for patients with secondary HPT were phosphate binders and vitamin D sterols, which may elevate calcium and/or phosphorus levels. As a consequence, treatment is frequently interrupted - resulting in inadequate control of PTH. Sensipar provides targeted treatment of secondary HPT with its unique mechanism of action that acts directly on the calcium-sensing receptor, the primary regulator of PTH.

"With cinacalcet HCl now available, there is no question that there is a large number of patients who need this therapy right away. We have a lot of patients whose disease is very poorly controlled and in our attempt to control their disease, we are producing side effects that are completely unacceptable," said Geoffrey Block, M.D., a lead investigator for the phase 3 trials and director of clinical research at Denver Nephrologists, PC. "In the clinical trials I have done with cinacalcet HCl, I have been astounded by how well this drug can control PTH, lower calcium and lower phosphorus. Patients for the first time are achieving levels of phosphorus that they recognize will protect their health over the long term."

Sensipar provides significant improvement over traditional therapy by bringing multiple parameters into NKF's K/DOQI clinical practice guidelines recommended target range at the same time.

"Achieving the new K/DOQI guidelines has been challenging with existing therapies, and has required clinicians to make tough decisions regarding therapeutic goals," said Brian Pereira, M.D., president and chief executive officer at the New England Health Care Foundation and professor of medicine at Tufts-New England Medical Center. "Sensipar gives the nephrology community an important new tool to help dialysis patients suffering from secondary HPT to achieve all four therapeutic target goals."

Parathyroid Carcinoma

Patients with parathyroid carcinoma have a rare, serious cancer of the parathyroid gland resulting in excess secretion of PTH, a form of primary HPT. The disease is complicated by elevated calcium levels in the blood. High calcium levels can lead to anxiety, depression, nausea, vomiting, bone fractures, kidney stones and in some cases coma. Surgical removal of the parathyroid gland is the only curative therapy for this disease but is not successful in all cases. Sensipar was shown to reduce high levels of calcium in patients with parathyroid carcinoma. With approximately 500 patients developing parathyroid carcinoma each year, Sensipar was granted orphan designation.

About Sensipar

In clinical trials in patients with secondary hyperparathyroidism on dialysis, Sensipar was safe and effective in reducing PTH, calcium-phosphorus product, calcium and phosphorus in a broad range of patients regardless of age, gender, race, years on dialysis or disease severity. Sensipar was effective in patients receiving vitamin D, as well as those not receiving vitamin D.

In clinical studies involving more than 1,100 patients, 40 percent of Sensipar patients and five percent of placebo patients receiving standard of care achieved PTH levels less than or equal to 250 pg/mL in the primary efficacy analysis. Secondary efficacy parameters also improved in patients treated with Sensipar. These studies showed that Sensipar reduced PTH while lowering calcium-phosphorus product, calcium and phosphorus levels. Reductions in PTH and calcium-phosphorus product were maintained for up to 12 months of treatment.

In a clinical trial in patients with hypercalcemia due to parathyroid carcinoma, Sensipar lowered calcium levels.

Based on its mechanism of action, Sensipar lowers calcium, so it should not be initiated if the calcium level is less than 8.4 mg/dL. During dose titration, calcium levels should be monitored frequently and if levels decrease below the normal range, appropriate steps should be taken to increase calcium levels. The threshold for seizures may be lowered by reductions in calcium levels and, infrequently, seizures have been reported, primarily in patients with a seizure history. The most commonly reported side effects are nausea and vomiting.

Amgen licensed Sensipar from NPS Pharmaceuticals Inc. in 1996. Amgen applied for regulatory approval in Australia, Canada, the European Union and New Zealand.

About Amgen

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

FORWARD LOOKING STATEMENTS

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended December 31, 2002, and in our periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, sales growth of recently launched products, difficulties or delays in manufacturing our products, and regulatory developments (domestic or foreign) involving current and future products and manufacturing facilities. In addition, sales of our products are affected by reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of our products. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We, or others could identify side effects or manufacturing problems with our products after they are on the market. 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. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. 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. Further, some raw materials, medical devices, and component parts for our products are supplied by sole third party suppliers.

For more information or the full prescribing information, please refer to the Amgen web site at www.amgen.com.

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