European Commission Approves Innovative First-in-Class Treatment for a Serious Complication of Chronic Kidney Disease

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Amgen Introduces Mimpara(R) Approved to Treat Secondary
Hyperparathyroidism in Chronic Kidney Disease Patients on Dialysis

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Oct. 28, 2004-- Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that its first-in-class oral calcimimetic, Mimpara(R) (cinacalcet), known as Sensipar(R) (cinacalcet HCl) in the United States (U.S.), has received regulatory approval in the European Union (EU). Mimpara is now authorized in the EU for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) on dialysis as well as for the treatment of elevated calcium levels in patients with cancer of the parathyroid gland.

"The approval of Mimpara in the EU is a significant advance in the management of secondary HPT," said Prof. Jorge Cannata, head of the Bone and Mineral Unit Hospital Central de Asturias, Oviedo, Spain. "Mimpara can help reduce parathyroid hormone while at the same time lower calcium and phosphorus levels, which is consistent with the K/DOQI(1) clinical practice guidelines for bone metabolism and disease in CKD."

The majority of an estimated 230,000 chronic kidney disease patients on dialysis in the EU suffer from SHPT. This serious disease is characterized by elevations in parathyroid hormone (PTH), and abnormal calcium and phosphorus levels. If left untreated, SHPT patients may develop severe bone disease, including bone pain and fractures. Traditional therapies for SHPT are often limited by increases in calcium and phosphorus. Elevations in calcium and phosphorus may lead to vascular and soft tissue calcifications. Abnormalities in PTH, calcium and phosphorus, which are the hallmark of SHPT, are associated with an increased risk of hospitalization and death, often due to cardiovascular disease.

Mimpara's unique mechanism of action acts directly on the calcium-sensing receptor located at parathyroid gland cells, the primary regulator of PTH, thereby providing targeted treatment of SHPT.

In clinical trials, Mimpara has been shown to lower simultaneously PTH, calcium, phosphorus and calcium phosphorus product levels resulting in a seven-fold increase in patients reaching K/DOQI target levels. With conventional therapy only eight percent of patients reach the four key K/DOQI target levels. In addition, post-hoc analyses of pooled data from six and 12 months clinical studies, Kaplan-Meier estimates of bone fracture and parathyroidectomy were lower in the cinacalcet group compared with the control group.

"Mimpara provides a new way of treating patients with secondary hyperparathyroidism without the limitations of previous therapies," said Beth Seidenberg, chief medical officer and senior vice president of global development at Amgen. "We are pleased to receive this approval earlier than anticipated. The unmet medical need of SHPT patients in the EU can now be satisfactorily and safely addressed with Mimpara."

Today's European Commission Decision follows a positive regulatory opinion for the approval of Mimpara in the EU, issued on July 29, 2004 by the Committee for Medicinal Products for Human Use (CHMP).

Mimpara is Amgen's first small molecule and represents an important milestone for the company. Mimpara is marketed as Sensipar(R) (cinacalcet HCl) in the U.S. and was approved by the Food and Drug Administration (FDA) in March 2004 for the treatment of secondary hyperparathyroidism in patients on dialysis and elevated calcium levels in patients with parathyroid carcinoma following a priority review.

Secondary Hyperparathyroidism

CKD is an irreversible condition characterized by decreased kidney function, which progresses over time. Most patients are not aware they have the disease until it becomes severe. If diagnosed and treated early, the progression of CKD may be slowed; however, if left untreated, the condition may progress to Stage 5 CKD (also referred to as end-stage renal disease), in which kidney function is no longer adequate to sustain life and requires dialysis or kidney transplantation. Without proper treatment to remove wastes and fluids from the bloodstream, Stage Five CKD is fatal. Some of the serious complications associated with CKD include cardiovascular disease, hypertension, anemia, bone disease, as well as SHPT.

As kidney function declines, the calcium and phosphorus balance in the body is upset, triggering the calcium-sensing receptor, the principal regulator of PTH secretion located on the surface of the parathyroid glands, to secrete too much PTH in an effort to restore balance. SHPT is a serious metabolic disorder characterized by an imbalance of PTH, calcium and phosphorus -- minerals vital to life and good bone health.

Management of SHPT can be challenging in part because it is difficult to lower PTH without the risk of increasing calcium-phosphorus product, calcium and phosphorus levels. Previously available treatments for patients with SHPT include phosphate binders and vitamin D sterols, which may elevate blood calcium levels. As a consequence, treatment is frequently interrupted -- resulting in inadequate control of PTH, which contributes to disease progression.

Parathyroid Carcinoma

Patients with parathyroid carcinoma have a rare, serious cancer of the parathyroid glands resulting in excess secretion of PTH. This 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 not successful in all cases.

About Mimpara

In clinical trials in SHPT patients on dialysis, Mimpara was well-tolerated and effective in reducing PTH, calcium, phosphorus calcium-phosphorus product in a broad range of patients regardless of age, gender, dialysis method (hemo- or peritoneal dialysis), years on dialysis or disease severity.

In a clinical trial in patients with hypercalcemia due to parathyroid carcinoma, Mimpara significantly lowered calcium levels in the majority of patients.

Based on its mechanism of action, Mimpara lowers calcium, so it should not be initiated if a patient's calcium levels are below the lower limit of the normal range. 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 Mimpara from NPS Pharmaceuticals Inc. in 1996. In addition to the EU and U.S., Mimpara has also been approved for use in Canada and submitted for approval in Australia 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, 2003, 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 first 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 US 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 first party suppliers.

EDITOR'S NOTE: An electronic version of this news release may be accessed via our Web site at www.amgen.com. Journalists and media representatives may sign up to receive all news releases electronically at time of announcement by filling out a short form in the Media section of the Web site.

(1)The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (K/DOQI) provides evidence- and opinion-based clinical practice guidelines for all phases of chronic kidney disease and related complications including bone metabolism and disease in CKD. K/DOQI is a registered trademark of the National Kidney Foundation, Inc.

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