Cinacalcet HCl Phase 3 Results Demonstrate Improvement in the Management of Secondary Hyperparathyroidism in Patients With Chronic Kidney Disease

November 15, 2003

Amgen's First Small Molecule - Cinacalcet HCl - Receives FDA Priority Review

SAN DIEGO, Nov. 15 -- Amgen (Nasdaq: AMGN), the world's largest biotechnology company, announced results of phase 3 studies evaluating the efficacy and safety of cinacalcet HCl, a first-in-class oral calcimimetic, administered once daily for the treatment of secondary hyperparathyroidism (HPT) associated with chronic kidney disease (CKD). These results were presented at an American Society of Nephrology (ASN) sponsored symposium in San Diego.

Amgen recently received notification that the U.S. Food and Drug Administration (FDA) granted a priority review for cinacalcet HCl, a novel therapeutic that modulates the activity of the calcium-sensing receptor, the primary regulator of PTH secretion. Cinacalcet HCl is the first investigational agent to demonstrate simultaneous reductions in parathyroid hormone (PTH), calcium-phosphorus product, phosphorus and calcium levels to successfully control secondary HPT. Moreover, cinacalcet HCl may allow patients to achieve PTH and mineral targets in accordance with the new Kidney Disease Outcomes Quality Initiative (K/DOQI) Guidelines for Bone Metabolism and Disease recently published by the National Kidney Foundation.

Secondary HPT develops early during the course of CKD and continues to progress as kidney function declines and patients begin dialysis. Patients with secondary HPT can suffer from bone disease, bone pain and fractures, soft tissue calcification and vascular calcification. The current treatment for patients with secondary HPT includes phosphate binders and vitamin D sterols, which may elevate blood calcium and/or phosphorus levels. As a consequence, treatment is frequently interrupted -- resulting in inadequate control of PTH, which contributes to disease progression.

"Cinacalcet HCl is an exciting new approach to treating secondary HPT," said Dr. Geoffrey A. Block, director of clinical research, Denver Nephrologists, PC. "Achieving the new K/DOQI guidelines will be challenging with existing therapies, which often require clinicians to make trade-offs regarding therapeutic goals. With cinacalcet HCl we may now have the ability to simultaneously maintain target levels of parathyroid hormone, calcium- phosphorus product, phosphorus and calcium."

Three phase 3 double-blind, randomized, placebo-controlled studies including more than 1,100 patients on hemodialysis and peritoneal dialysis with uncontrolled secondary HPT were conducted in Australia, Canada, Europe and the U.S. Cinacalcet HCl was titrated to achieve a target PTH level, which is within the new K/DOQI guidelines. A greater proportion of patients in the cinacalcet HCl group (36 to 48 percent), compared to those receiving standard therapy (four to seven percent) achieved the primary endpoint of PTH less than or equal to 250 pg/mL. Across the phase 3 program, clinically relevant reductions in calcium-phosphorus product (13 to 17 percent) calcium (six to eight percent) and phosphorus (seven to 10 percent) occurred in patients receiving cinacalcet HCl, while they remained at baseline levels in those receiving standard therapy and placebo. In a separate study in patients with CKD not requiring dialysis, cinacalcet HCl resulted in reductions in PTH comparable to those observed in patients with end-stage renal disease receiving dialysis.

Cinacalcet HCl was highly efficacious regardless of age, gender, race or disease severity. Cinacalcet HCl was also effective in patients receiving vitamin D as well as those contraindicated to vitamin D due to hypercalcemia or hyperphophatemia. The most commonly reported side effects in the clinical trials with cinacalcet HCl were nausea and vomiting, which were generally mild to moderate in severity and brief in duration.

"We are pleased that cinacalcet HCl, the company's first small molecule, has received priority review by the FDA. This represents an important milestone for Amgen, furthering the company's commitment to the patients suffering from CKD," said Dr. Beth Seidenberg, senior vice president of development and chief medical officer at Amgen.

Amgen licensed cinacalcet HCl from NPS Pharmaceuticals Inc. and filed a new drug application (NDA) with the FDA for cinacalcet HCl. Additionally, Amgen has filed cinacalcet HCl for regulatory approval in Australia, Canada, the European Union and New Zealand.

Forward Looking Statement

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 US legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of our product. 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.

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.

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