



## Sensipar Pivotal Studies in over 700 Patients Published in New England Journal of Medicine

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Study Validates Use of Innovative, First-in-Class Treatment for Chronic Kidney Disease Patients on Dialysis Suffering from Secondary Hyperparathyroidism-- THOUSAND OAKS, Calif--April 8, 2004-- Data published in this week's issue of the New England Journal of Medicine (NEJM) demonstrate that Sensipar (cinacalcet HCl), effectively reduces parathyroid hormone (PTH) levels in patients on dialysis with secondary hyperparathyroidism (secondary HPT) and lowers elevated calcium and phosphorus levels. These elevations in bone minerals have been associated with serious adverse clinical outcomes, including an increased risk for cardiovascular death. Treatment strategies that include the recently approved Sensipar may make it possible to achieve the more stringent therapeutic guidelines now recommended for managing secondary HPT.

"Secondary HPT is a major problem affecting the majority of dialysis patients and is one of the most difficult challenges physicians face on a day-to-day basis in taking care of these patients," said Geoffrey A. Block, M.D., lead author and director of clinical research at Denver Nephrologists, PC. "Sensipar represents an important therapeutic development. Physicians will now be able to safely and effectively reduce PTH levels without increasing levels of calcium and phosphorus making it possible to achieve recommended therapeutic goals."

A total of 741 chronic kidney disease patients on dialysis with uncontrolled secondary hyperparathyroidism despite traditional treatment participated in two studies. At the conclusion of these studies, 43 percent of patients in the Sensipar group achieved the primary end point with a mean PTH level of 250 picograms per milliliter (pg/mL) or less; only five percent in the placebo group reached the same endpoint. In addition, mean parathyroid hormone levels decreased by 30 percent or more in 64 percent of patients given Sensipar, as compared with only 11 percent of those given placebo. In addition, calcium-phosphorus product levels declined by fifteen percent in the Sensipar group and remained unchanged in the placebo group. Eighty-nine percent of the patients receiving Sensipar who reached the primary end point had a concurrent reduction in calcium-phosphorus product.

"The ability to selectively target the molecular mechanism that controls the disease represents a remarkable development both scientifically and clinically. The availability of this new agent will provide greater flexibility in the overall management of these patients," stated William G. Goodman, study author and professor of medicine at the University of California at Los Angeles School of Medicine. "Patients and physicians should be encouraged by the results of this study and the availability of this product. I expect Sensipar will be able to dramatically improve the quality of the care we provide to dialysis patients who suffer from this debilitating disease."

Secondary HPT is a metabolic disorder in patients with chronic kidney disease (CKD) characterized by elevations in PTH, calcium and phosphorus levels. Affecting more than 300,000 patients, secondary HPT develops early during the course of CKD and progresses as renal function declines and patients begin dialysis. If left untreated, secondary HPT can lead to bone disease, bone pain and fractures, and vascular and soft tissue calcifications, which are associated with an increased risk of hospitalization and death.

Sensipar is the only available therapy that allows practitioners to reduce PTH while simultaneously lowering calcium-phosphorus product, calcium and phosphorus in accordance 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. These guidelines were developed in response to the strong correlation between these biochemical parameters and morbidity and mortality in the CKD population.

### Study Design

Two identical randomized, double-blind placebo-controlled clinical trials were conducted in 125 sites worldwide in 741 patients suffering from secondary HPT who had been treated with thrice-weekly hemodialysis for at least three months. Patients were randomized to receive either Sensipar (371 patients) or placebo (370 patients) for 26 weeks. Once-daily doses were increased from 30 mg to 180 mg to achieve intact parathyroid hormone levels of 250 pg/mL or less, a value generally considered to reflect adequate control of secondary HPT.

### About Sensipar

Sensipar is an innovative, first-in-class oral calcimimetic indicated for the treatment of secondary HPT in CKD patients on dialysis and for the treatment of elevated calcium levels (hypercalcemia) in patients with parathyroid carcinoma. On March 8, 2004, after a priority review, Sensipar was approved for marketing by the U.S. Food and Drug Administration.

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 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.

For more information or the full prescribing information, please refer to the Sensipar Web site at [www.Sensipar.com](http://www.Sensipar.com).

About Amgen

Amgen Inc. (Nasdaq:AMGN) 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.

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