Mimpara -- Cinacalcet HCl -- Receives Positive Regulatory Opinion for Approval in Europe

July 30, 2004

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--July 29, 2004--Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion to approve marketing authorization for Mimpara(R) (cinacalcet HCl) in the European Union (EU) for the treatment of secondary hyperparathyroidism (HPT) in chronic kidney disease (CKD) patients on dialysis and the treatment of elevated calcium levels (hypercalcemia) in patients with parathyroid carcinoma. In the U.S., the drug is marketed as Sensipar(TM) and was approved by the Food and Drug Administration (FDA) following a priority review in March 2004. Mimpara is an innovative, oral calcimimetic, which directly lowers parathyroid hormone levels by increasing sensitivity of the calcium-sensing receptor to extracellular calcium.

"Amgen is proud to offer this innovative, first-in-class medicine to help meet a significant medical need for patients on dialysis and those with cancer of the parathyroid gland," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development at Amgen. "Once approved, Mimpara will be the only available therapy in the EU that allows physicians to safely and effectively reduce PTH while simultaneously lowering calcium-phosphorus product, calcium and phosphorus."

Mimpara is Amgen's first small molecule therapeutic and represents an important milestone for the company in the EU. It also represents a potentially significant advance for CKD patients on dialysis with secondary HPT, a metabolic disorder characterized by elevations in PTH, calcium and phosphorus levels, and for those with hypercalcemia due to parathyroid carcinoma, a rare, serious cancer of the parathyroid gland resulting in excess secretion of PTH.

Left untreated, patients with secondary HPT can suffer from bone disease, bone pain and fractures, soft tissue calcification, vascular calcification and cardiovascular complications. High calcium levels due to parathyroid carcinoma can lead to anxiety, depression, nausea, vomiting, bone fractures, kidney stones and in some cases coma.

Recommendations from the CHMP are typically endorsed by the European Commission for marketing authorization within three to four months.

About Mimpara

In clinical trials in patients with HPT on dialysis, Mimpara 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. Mimpara was effective both in patients receiving and not receiving vitamin D.

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

Based on its mechanism of action, Mimpara lowers calcium, so it should not be initiated if a patient's 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 Mimpara from NPS Pharmaceuticals Inc. in 1996. In March 2004, the FDA approved cinacalcet HCl, which is marketed as Sensipar in the U.S. Amgen has also applied for regulatory approval in Australia, Canada 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 Amgen's Form 10-K for the year ended December 31, 2003, and in Amgen's 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. 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 side effects or manufacturing problems with our products after they are on the market. In addition, sales of our products are affected by the availability of reimbursement and the 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. 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 it 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.

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. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Further, the scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (FDA) for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses. Only the FDA can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

An electronic version of this news release may be accessed via our Web site at www.amgen.com. Visit the Corporate Center and click on Amgen News. Journalists and media representatives may sign up to receive all news releases electronically at the time of announcement by filling out a short form in the Amgen News section of the Web site.

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