Amgen Launches Landmark Trial to Evaluate the Impact of Treating Anemia on Cardiovascular Risks in Patients with Chronic Kidney Disease and Type 2 Diabetes

November 1, 2004

ST. LOUIS--(BUSINESS WIRE)--Nov. 1, 2004--

Sensipar(R) (cinacalcet HCl) Data Also Presented at American Society of Nephrology Meeting Underscores Amgen's Commitment to Chronic Kidney

Disease Patients with Secondary Hyperparathyroidism

Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that the company has initiated a landmark trial to evaluate the impact of treating anemia on cardiovascular outcomes in patients with chronic kidney disease (CKD) and type 2 diabetes. TREAT (Trial to Reduce cardiovascular Events with Aranesp(R) (darbepoetin alfa) Therapy) is one of the largest clinical trials in the company's 25-year history. The TREAT study design as well as additional Sensipar(R) data was presented at the American Society of Nephrology (ASN) annual meeting in St. Louis.

"Current research suggests that anemia is an augmenter of cardiovascular risk in individuals with CKD and type 2 diabetes," said TREAT lead investigator Marc Pfeffer, M.D., Ph.D., chief of medicine at Brigham and Women's Hospital and a professor at Harvard Medical School. "TREAT will be the definitive study to determine if treating anemia with Aranesp does, in fact, lower the risk of death and non-fatal cardiovascular events in individuals with CKD and type 2 diabetes."

TREAT is an international 4,000 patient, multicenter, randomized, double-blind, placebo-controlled trial. The primary endpoint of TREAT is a composite index of time to mortality or non-fatal cardiovascular event, including myocardial infarction, myocardial ischemia, stroke and heart failure.

Anemia is a common complication of CKD and becomes more common as kidney function declines. Aranesp has been shown to be effective in correcting anemia with less frequent dosing than other treatments. In TREAT, patients will receive Aranesp once monthly, which is the same dosing approved by the European Committee for Medicinal Products for Human Use (CHMP) in August 2004. In the U.S., Aranesp is approved to be administered once a week if a patient was receiving Epoetin alfa two to three times weekly. Aranesp should be administered once every two weeks if a patient was receiving Epoetin alfa once per week.

"The work surrounding the initiation of TREAT and the continued studies for Sensipar demonstrate Amgen's commitment to treating grievous illnesses and improving the lives of patients with chronic kidney disease," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development at Amgen.

Sensipar for the Treatment of Secondary Hyperparathyroidism (HPT)

in CKD Patients on Dialysis

Additional study results presented at ASN collectively confirm that Sensipar enables significantly more patients to achieve the four key National Kidney Foundation Kidney Disease Outcomes Quality Initiative (K/DOQI) bone metabolism and disease goals independent of vitamin D dose. Sensipar data from 210 patients in the phase 3 studies demonstrated that Sensipar sustained reductions in parathyroid hormone (PTH) and calcium-phosphorus product out to one year of treatment. In two additional phase 3b studies where vitamin D doses were reduced, Sensipar enabled significantly more patients to achieve the K/DOQI targets for PTH and calcium-phosphorus product as compared to the baseline values. In one 3b study, Sensipar was highly effective in controlling PTH while simultaneously lowering calcium-phosphorus product in patients who were within the K/DOQI target range for PTH but above the range for calcium-phosphorus product.

"The one-year study results further confirm that Sensipar effectively lowers PTH and the calcium-phosphorus product offering dialysis patients the benefit of long-term control of secondary HPT," said David Bushinsky, M.D., study investigator, University of Rochester. "The additional clinical trials emphasize that Sensipar simultaneously controls the four key parameters, PTH, calcium-phosphorus product, calcium and phosphorus, of secondary HPT and is efficacious with small doses of vitamin D."

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 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.

Secondary HPT is characterized by elevations in PTH, calcium and phosphorus levels. If left untreated, patients with secondary HPT can develop bone disease, bone pain and fractures, vascular and soft tissue calcifications, which are frequently associated with an increased risk of hospitalization and death. According to Dr. Bushinsky, "we expect that achieving the K/DOQI targets will be associated with better clinical outcomes."

On October 26, the European Medicines Evaluation Agency approved marketing authorization in the European Union (EU) following a positive opinion issued in July from the CHMP. The drug will be marketed as Mimpara(R) (cinacalcet) in the EU.

About Aranesp

Aranesp(R) is a recombinant erythropoietic protein (a protein that stimulates production of oxygen-carrying red blood cells). Amgen revolutionized anemia treatment with the discovery of recombinant erythropoietin, epoetin alfa, which is currently marketed in the U.S. by Amgen as EPOGEN(R) (Epoetin alfa)(i) and by Ortho Biotech Products, LP, as Procrit(R) (Epoetin alfa)(ii). Building on this heritage, Amgen developed Aranesp, which contains two additional sialic acid-containing carbohydrate chains than the Epoetin alfa molecule, resulting in more activity, with the added benefit of less-frequent administration.

Aranesp was approved by the U.S. Food and Drug Administration (FDA) in September 2001 for the treatment of anemia associated with chronic renal failure, also known as CKD, for patients on dialysis and patients not on dialysis. In July 2002, Aranesp was approved by the FDA for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies.

Aranesp is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic and other serious events; dose reductions are recommended if the hemoglobin increase exceeds 1.0 g/dL in any two-week period. The most commonly reported side effects in Aranesp(R) trials were fatigue, edema, nausea, vomiting, diarrhea, fever and dyspnea.

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 HPT 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.

Sensipar is safe and well-tolerated in a broad range of patients. Sensipar lowers serum calcium. Significant reductions in calcium may lower the threshold for seizures. Secondary HPT patients, particularly those with a history of a seizure disorder, should be carefully monitored for the occurrence of low serum calcium or symptoms of hypocalcemia. The most commonly reported side effects were nausea and vomiting.

Amgen licensed Sensipar from NPS Pharmaceuticals Inc. in 1996. Amgen has applied for regulatory approval in Australia and New Zealand. Approval has been granted in Canada.

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.

Note: Copies of the study abstracts are available upon request. Full prescribing information is available on the Web for Aranesp(R) at www.aranesp.com and for Sensipar(R) at www.sensipar.com.

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.

(i)EPOGEN(R) is a registered trademark of Amgen Inc.

(ii)Procrit(R) is a registered trademark of Ortho Biotech Products, L.P.

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