Amgen Announces EVOLVE Trial(TM) To Investigate Impact of Sensipar(R)/Mimpara(R) (cinacalcet HCl) on Mortality and Cardiovascular Morbidity in Secondary Hyperparathyroidism Patients With Chronic Kidney Disease Receiving Dialysis

July 16, 2006

GLASGOW, Scotland--(BUSINESS WIRE)--July 16, 2006-- -- New Data Showed Earlier Intervention With Sensipar/Mimpara Improved Ability to Achieve K/DOQI(TM) Secondary HPT Treatment Guidelines in Dialysis Patients --

Amgen (Nasdaq:AMGN), the world's largest biotechnology company, announced today the initiation of the largest prospective, randomized clinical trial planned to date in patients with stage five chronic kidney disease (CKD). EVOLVE (EValuation Of Cinacalcet Therapy to Lower CardioVascular Events)(TM) is a Phase 3 international, clinical outcomes study designed to determine whether Sensipar(R)/Mimpara(R) (cinacalcet HCl) can effectively reduce the risk of mortality and cardiovascular morbidity in patients with secondary hyperparathyroidism (secondary HPT) and CKD undergoing maintenance dialysis. EVOLVE was announced at the 2006 European Renal Association - European Dialysis and Transplant Association (ERA-EDTA). Cinacalcet HCl is marketed as Sensipar in the United States, Canada and Australia and as Mimpara in the European Union.

Amgen's decision to initiate EVOLVE is supported by a recent post-hoc analysis of four pooled, prospective, randomized, placebo-controlled clinical trials that showed treatment with cinacalcet HCl in patients with secondary HPT and CKD receiving dialysis resulted in improvement of clinical outcomes, including cardiovascular hospitalization, parathyroidectomy, fracture and health-related quality of life.(1)

"Recent data have shown a relationship between poorly controlled secondary HPT and increased mortality and morbidity in CKD patients receiving dialysis," said Willard Dere, MD, senior vice president for global development and chief medical officer at Amgen. "Until EVOLVE, no robust prospective, clinical trial has definitively determined whether treating secondary HPT reduces the risk of cardiovascular events. The results of the EVOLVE will be invaluable to nephrologists in deciding how to optimally manage secondary HPT."

EVOLVE is expected to enroll approximately 3,800 patients in 500 clinical sites throughout the world, including the United States, Latin America, Canada, Australia, Russia and the European Union. Amgen has gained acceptance of the study design with global regulatory authorities and enrollment is expected to begin in the second half of 2006.

At ERA-EDTA, Amgen also announced new cinacalcet HCl data from the OPTIMA Study (An OPen-label, Randomized Study Using Cinacalcet To IMprove Achievement of K/DOQI(TM) Targets in Patients with ESRD). This study showed that initiation of cinacalcet HCl at the earlier stages of secondary HPT at intact parathyroid hormone (iPTH) levels of 300-500 pg/mL enabled greater achievement of the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines for secondary HPT targets than if treatment was initiated at higher iPTH levels. The K/DOQI guidelines are evidence-based clinical practice guidelines for kidney dialysis patients. Additionally, cinacalcet HCl helped more patients achieve K/DOQI(TM) targets for iPTH and calcium-phosphorous product (Ca x P) levels compared to conventional therapy (with unrestricted vitamin D and phosphate binder use). Control of both PTH and Ca x P was greatest in patients with lower baseline PTH and was achieved with lower cinacalcet HCl doses.(2)

"Use of Mimpara in dialysis patients enables patients and physicians to achieve greater control of secondary HPT, especially when adequate treatment is initiated in the early stages of this progressive metabolic disorder," said Martin Wilkie, MD, Northern General Hospital, Sheffield, United Kingdom. "In our study, we found that the greatest reductions in Ca and P were in those patients receiving Mimpara in combination with lower doses of vitamin D sterols. Furthermore, large Phase 3 outcomes clinical studies are needed to determine Mimpara's benefits in improving patients' lives and preventing disease progression."

About EVOLVE and Amgen Cardiovascular Clinical Trials Program

Amgen has initiated an extensive clinical trials program to study the effect of treating CKD complications or anemia on cardiovascular outcomes in different populations. In addition to EVOLVE, Amgen initiated TREAT (Trial to Reduce Cardiovascular Events with Aranesp Therapy)(TM), which is an ongoing trial in diabetic patients with chronic kidney disease and anemia not requiring dialysis, and the RED-HF(TM) Trial (Reduction of Events with Darbepoetin alfa in Heart Failure) to evaluate treatment of anemia with Aranesp on morbidity and mortality in patients with symptomatic heart failure.

About OPTIMA Data Presented At ERA-EDTA

The study involved 552 dialysis patients with baseline (BL) iPTH 300-800 pg/mL, randomized to receive either cinacalcet HCl or conventional therapy (CT) in a ratio of 2:1. Cinacalcet HCl patients were initiated at 30 mg/day and titrated to achieve iPTH Less Than or Equal to 300 pg/mL. After reaching iPTH target, vitamin D dose was decreased if necessary to achieve Ca x P target. In the CT arm, physicians had full freedom to treat patients with unrestricted vitamin D and phosphate binder use in an attempt to reach treatment targets. All patients were assessed during an efficacy assessment phase (weeks 17 to 23). More cinacalcet HCl patients with moderate BL iPTH levels (300 - 500 pg/mL) met both iPTH and Ca x P targets (65 percent) than cinacalcet HCl patients with high BL iPTH levels (500 - 800 pg/mL; 55 percent) and CT patients (16 percent). Mean daily dose of cinacalcet HCl was also lower among patients with moderate than high BL iPTH levels (42 mg vs. 60 mg).(2)

Secondary HPT, Chronic Kidney Disease and Cardiovascular Disease

There are approximately 1.3 million patients worldwide currently on dialysis to treat kidney failure(3) and nearly all of them also have secondary HPT.(4) Secondary HPT is characterized by increased levels of parathyroid hormone (PTH), calcium and phosphorus. If left untreated, patients with secondary HPT may develop severe bone disease, including bone pain and fractures.(4)

Abnormalities in PTH, calcium and phosphorus are also associated with an increased risk of hospitalization and death, often due to cardiovascular disease.(4) According to the NKF, cardiovascular disease is the leading cause of death among dialysis patients.(5)

About Sensipar/Mimpara (cinacalcet HCl)

In clinical trials in secondary HPT patients on dialysis, cinacalcet HCl was well-tolerated and effective in reducing PTH, Ca, P, Ca x P in a broad range of patients regardless of age, gender, dialysis method (hemo- or peritoneal dialysis), years on dialysis or disease severity.(6)

In a clinical trial in patients with hypercalcemia due to parathyroid carcinoma, cinacalcet HCl significantly lowered calcium levels in the majority of patients.(7)

Studies have shown that cinacalcet HCl lowers Ca, based on its mechanism of action, so it should not be initiated if a patient's Ca levels are below the lower limit of the normal range.(7) During dose titration, Ca levels should be monitored frequently and if levels decrease below the normal range, appropriate steps should be taken to increase Ca levels. The threshold for seizures may be lowered by reductions in Ca levels and, infrequently, seizures have been reported. The most commonly reported side effects are nausea and vomiting.(7)

About Amgen

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a broad and deep pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

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 Amgen's Form 10-K for the year ended December 31, 2005, 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 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.

(1)Cunningham J, Danese M, Olson K, Klassen P, Chertow G.M. Kidney Int.: 1793-1800, 2005.

(2)Messa P, Villa G, Braun J, et al. European Renal Association - European Dialysis and Transplant Association (ERA-EDTA)

(3)Lameire N., Jager K., van Biesen W., et al: Chronic kidney disease. Kidney Int,.68:99:30-38, 2005

(4)De Francisco AL. Clin Ther 2004; 26: 1976-1993.

(5)National Kidney Foundation. Available at: http://www.kidney.org/professionals/kdoqi/guidelines_cvd/overview.htm

(6)Moe SM, et al. Kidney Int.: 2005; 760-771

(7)Mimpara(R) Summary of Product Characteristics

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SOURCE: Amgen