Landmark Trial Will Evaluate the Impact of Treating Anemia on Cardiovascular Outcomes in Patients with Chronic Kidney Disease and Type 2 Diabetes

March 28, 2005

TREAT Study Highlighted in March American Heart Journal

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--March 28, 2005-- Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that TREAT (Trial to Reduce Cardiovascular Events with Aranesp(R) Therapy), an Amgen-sponsored trial, is featured in the March 2005 issue of the American Heart Journal. TREAT is the first randomized controlled trial specifically designed to determine whether treating anemia reduces cardiovascular events in individuals with chronic kidney disease (CKD) and Type 2 diabetes.

"Existing data suggest that anemia increases the risk of cardiovascular events in patients with chronic kidney disease and Type 2 diabetes," said TREAT lead investigator, Marc Pfeffer, M.D., Ph.D., Interim Chief of Medicine at Brigham and Women's Hospital and Professor at Harvard Medical School. "The inclusion of the TREAT rationale and methodology in the American Heart Journal highlights the cardiology community's recognition of the need to further understand and study the link between chronic kidney disease, diabetes, anemia and cardiovascular disease."

According to the American Heart Association, people with CKD, even those in the early stages of the disorder, are in the highest-risk group for cardiovascular disease. Recent data show that the majority of CKD patients die before they ever reach dialysis. The increased cardiovascular risk found in patients with CKD is attributable to several risk factors, including anemia. Anemia is a common complication of CKD that worsens as kidney function declines.

The American Heart Journal article reviews the role of diabetes and anemia in cardiovascular disease among patients with CKD and provides the rationale for designing and conducting TREAT, which is an international 4,000 patient, multicenter, randomized, double-blind, placebo-controlled trial. Additionally, the article explains the primary endpoint of TREAT to be a composite index of time to mortality or non-fatal cardiovascular events, including myocardial infarction, myocardial ischemia, stroke and heart failure.

"We are committed to serving patients as they manage these chronic diseases and are excited to bring such an important clinical trial to the medical community," said Willard Dere, senior vice president and chief medical officer at Amgen. "TREAT is designed to definitively determine whether treating anemia reduces cardiovascular events in patients with chronic kidney disease and Type 2 diabetes."

Aranesp(R) (darbepoetin alfa) has been shown to be effective in correcting anemia with less frequent dosing than other treatments. In the U.S., Aranesp is approved to be administered once a week if a patient received Epoetin alfa two to three times weekly. The European Committee for Medicinal Products for Human Use (CHMP) approved once a month dosing in August 2004. Patients participating in TREAT will receive Aranesp once monthly. Aranesp should be administered once every two weeks if a patient received Epoetin alfa once per week.

There are TREAT study sites planned across the globe. Patients and physicians can access www.amgentrials.com for more information about TREAT.

About Aranesp(R) (darbepoetin alfa)

Aranesp is a recombinant erythropoietic protein (a protein that stimulates production of oxygen-carrying red blood cells). Amgen revolutionized anemia treatment with the development 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 and patients with known hypersensitivity to the active substance or any of the excipients. 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 trials were fatigue, edema, nausea, vomiting, diarrhea, fever and dyspnea.

The Aranesp dosage should be adjusted for each patient to achieve and maintain a target hemoglobin not to exceed 12 g/dL. Doses must be individualized to ensure that hemoglobin is maintained at an appropriate level for each patient.

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 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, 2004, 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 US 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.

Full prescribing information for Aranesp(R) is available at www.aranesp.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.

CONTACT: Amgen, Thousand Oaks
Keith Givens, 805-447-4587 (media)
Laura Biswas, 805-447-1060 (investors)

SOURCE: Amgen