Data Show Aranesp(R) (Darbepoetin Alfa) Administered Once Monthly Maintains Hemoglobin Levels in Chronic Kidney Disease Patients with Anemia

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Results Presented at the American Society of Nephrology 2005 Annual Meeting Add to the Growing Body of Evidence Examining Administration of Aranesp at Extended Dosing Intervals

PHILADELPHIA, Nov 12, 2005 (BUSINESS WIRE) -- Amgen (NASDAQ:AMGN), the world's largest biotechnology company, today announced results from a study by Silver et al. that indicates Aranesp(R) (darbepoetin alfa) administered once-monthly (QM) maintained stable hemoglobin control in chronic kidney disease (CKD) patients with anemia not receiving dialysis, who were previously receiving Aranesp dosed every other week (Q2W). Eighty-five percent of the patients who completed the study successfully maintained hemoglobin (Hb) levels of greater than or equal to 11g/dL (Poster #SA-PO940). The data were presented today at the American Society of Nephrology (ASN) annual meeting. Amgen expects to file new data with the U.S. Food and Drug Administration (FDA) on extended dosing regimens for Aranesp in CKD by the end of 2005.

"These results confirm previously published data that also show once-monthly Aranesp administration maintains stable hemoglobin control," said Marcia R. Silver, M.D., FACP, director, Hemodialysis Program Division of Nephrology and Hypertension, MetroHealth Medical Center, and associate professor of Medicine, Case Western Reserve University. "Administering Aranesp once-monthly provides patients, physicians and nurses with significant advantages, as it allows CKD-related anemia to be treated more conveniently with fewer office visits."

This 33-week study enrolled 152 patients who had Hb levels 11 to 13 g/dL and estimated glomerular filtration rate (eGFR) greater than or equal to 15 mL/min and less than or equal to 60 mL/min, were iron replete and were receiving stable doses of Aranesp Q2W. Upon enrollment, the frequency of Aranesp administration was extended to once-monthly. The initial Aranesp once-monthly dose was equivalent to the individual subject's total dose in the month preceding enrollment. Doses were then titrated to maintain Hb levels within a 11 to 13 g/dL range.

"Amgen has a strong history of developing innovative therapies for the treatment of anemia," said Will Dere, M.D., senior vice president of Global Development and chief medical officer at Amgen. "We continue to pursue ways to improve the lives of CKD patients, and exploring extended dosing intervals of Aranesp, such as once-monthly, is a powerful example of our commitment to these patients."

Most adverse events (AEs) were mild to moderate in severity and no patients reported treatment-related serious and life-threatening AEs. The most common AEs were back pain, peripheral edema and nasopharyngitis (seven percent of subjects for each event), which are consistent with previous studies.

Anemia and Chronic Kidney Disease (CKD)

According to the National Kidney Foundation, CKD affects 20 million Americans (one in nine adults) and more than 20 million others are at increased risk for developing kidney disease. CKD is an irreversible condition characterized by kidney damage and impaired function that often progresses over time. Patients with CKD often suffer from serious complications such as anemia, which occurs when failing kidneys no longer produce sufficient erythropoietin, a hormone that stimulates the production of oxygen-carrying red blood cells (RBCs). RBCs contain hemoglobin, a red, iron-rich protein that carries oxygen from the lungs to all of the body's tissues. Oxygen provides the energy the body needs for normal activities. Anemia occurs when the number of RBCs (or the Hb in them) falls below normal (12 to 18 grams/deciliter of blood). Therefore, the body gets less oxygen and does not have enough energy to function properly.

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 a recombinant human 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. Like all other protein-based erythopoiesis stimulating agents (ESAs), including endogenous erythropoietin, Aranesp stimulates erythropoesis through the epoetin (EPO) receptor.

Aranesp was approved by the 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 has been effectively used in over 500,000 anemic patients since its launch in 2002 and has an established safety profile.

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. Pure red cell aplasia (PRCA) has been observed in patients treated with recombinant erythropoietins. Aranesp should be discontinued in any patient with evidence of PRCA and the patient evaluated for the presence of antibodies to erythropoietic products. The most commonly reported side effects in Aranesp trials were fatigue, edema, nausea, vomiting, diarrhea, fever and dyspnea. Aranesp dosage should be adjusted for each patient to achieve and maintain a target hemoglobin level 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 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 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, 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 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.

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, LP

SOURCE: Amgen

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