



FDA Approves Extended Dosing of Aranesp(R) to Treat Chemotherapy-Induced Anemia; Every-Three-Week Dosing Can Provide Added Convenience, Potentially Reducing Number of Clinic Visits and Injections for Anemia Treatment

March 27, 2006

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--March 27, 2006--Amgen (NASDAQ:AMGN), the world's largest biotechnology company, today announced the U.S. Food and Drug Administration (FDA) has approved every-three-week dosing of Aranesp(R) (darbepoetin alfa) for the treatment of chemotherapy-induced anemia (low red blood cell count) in patients with non-myeloid malignancies. Aranesp is the only erythropoiesis-stimulating agent approved by the FDA for every-three-week administration.

"Amgen developed Aranesp to provide cancer patients with a long-acting and effective means to treat chemotherapy-induced anemia, a common side effect of chemotherapy," said Willard Dere, M.D., chief medical officer and senior vice president of Global Development at Amgen. "The approval of an extended dosing protocol for Aranesp is an important milestone allowing anemia treatment to be synchronized with both weekly and every-three-week chemotherapy, which are the most commonly used treatment regimens. This offers improved convenience for patients and less injection-related burden for patients and healthcare professionals compared to weekly anemia treatment."

Anemia can negatively affect patients and impact their daily activities. This can often manifest as fatigue, trouble breathing or rapid heartbeat, chest pain, dizziness or lightheadedness, inability to concentrate, headache, inability to stay warm, loss of sex drive, and pale skin. Frequent visits to the clinic for anemia treatment can result in significant time spent by patients, caregivers and healthcare providers. Reducing the number of visits required for anemia treatment with less frequent dosing and trying to synchronize anemia treatment with other naturally occurring visits could reduce the amount of patient and caregiver time required for anemia treatment.

"In clinical studies, Aranesp has proven effective in reducing the incidence of red blood cell transfusions and boosting and maintaining target hemoglobin levels when administered every three weeks," said Ralph Boccia, M.D., director of clinical research, Center for Cancer and Blood Disorders, Bethesda, MD. "Now, this less frequent dosing means patients can visit the doctor less frequently, which can result in less time away from loved ones and daily activities."

The update to the Aranesp label now includes a recommended starting dose of 500 mcg once every three weeks in addition to the recommended starting dose of 2.25 mcg/kg once weekly. The new dosing recommendations are based on a randomized, double-blind, phase 3 study that evaluated the safety and effectiveness of every-three-week administration of Aranesp. Patients with chemotherapy-induced anemia were randomized to receive 500 mcg of Aranesp every three weeks (n=353) or 2.25 mcg/kg (n=352) administered weekly for up to 15 weeks. In both groups, the starting dose was reduced by 40 percent if hemoglobin levels increased by more than 1 g/dL in a 14-day period, and Aranesp was withheld if hemoglobin levels exceeded 13 g/dL. More than 70 percent of patients in the every-three-week group required dose reductions, resulting in an average weekly dose of 125 mcg for the patients in this group.

About Chemotherapy-Induced Anemia

Chemotherapy can reduce the bone marrow's ability to produce red blood cells that transport oxygen from the lungs to all of the body's muscles and organs. Anemia occurs when there are too few red blood cells and the body's tissues are "starved" of oxygen, which can make a patient feel short of breath, very weak, faint and tired.

This year, an estimated 1.3 million cancer patients will undergo chemotherapy in the United States; approximately 800,000 (67 percent) will become anemic. More than half of chemotherapy patients report that fatigue, a common symptom of anemia, affects their daily lives more than any other side effect of treatment, including nausea, pain and depression.

Although anemia is one of the most common side effects of chemotherapy, it is often not recognized and frequently under-treated, despite treatments that have been available for more than a decade. In fact, approximately half of patients with a hemoglobin level less than the recommended target level of 11 to 12 g/dL in the National Comprehensive Cancer Network(R) (NCCN) guidelines for "Cancer and Treatment-Related Anemia" are never treated with erythropoietic therapy.

About Aranesp

Amgen revolutionized anemia treatment with the development of Epoetin alfa, a recombinant erythropoietin (a protein that stimulates the production of oxygen-carrying red blood cells). Building on this heritage, Amgen developed Aranesp, a unique erythropoiesis-stimulating protein that can be dosed less frequently.

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 (CRF), also known as chronic kidney disease (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 non-myeloid malignancies. Since its introduction in 2001, more than 1.7 million CKD and chemotherapy patients with anemia have received treatment with Aranesp.

Important Safety Information

Aranesp is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic events and other serious events. The target hemoglobin (Hb) should not exceed 12 g/dL. If the Hb increase exceeds 1.0 g/dL in any 2-week period, dose reductions are recommended. In a study with another erythropoietic product, where the target Hb was 12-14 g/dL, an increased incidence of thrombotic events, disease progression and mortality was seen.

Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias associated with neutralizing antibodies to erythropoietin

have been reported in patients treated with Aranesp. This has been reported predominately in patients with CRF receiving Aranesp by subcutaneous administration. A sudden loss of response to Aranesp, accompanied by severe anemia and low reticulocyte count, should be evaluated. If anti-erythropoietin antibody-associated anemia is suspected, withhold Aranesp and other erythropoietic proteins. Aranesp should be permanently discontinued in patients with antibody-mediated anemia. Patients should not be switched to other erythropoietic proteins.

The most commonly reported side effects in clinical trials were fatigue, edema, nausea, vomiting, diarrhea, fever and dyspnea.

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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify side effects or manufacturing problems with Amgen's products after they are on the market. In addition, sales of Amgen's 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 Amgen's products. In addition, Amgen competes with other companies with respect to some of Amgen's marketed products as well as for the discovery and development of new products. Amgen believes that some of the newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen 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 Amgen routinely obtains patents for Amgen's products and technology, the protection offered by Amgen's patents and patent applications may be challenged, invalidated or circumvented by Amgen's competitors and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for Amgen's products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of Amgen's existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of Amgen's products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's 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.

Aranesp prescribing information can be accessed by calling 800-772-6436 or by logging on to 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.

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