Data Show Efficacy of Extended Dosing of Aranesp(R) in the Treatment of Chemotherapy-Induced Anemia

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Aranesp with Supplemental Iron More Effective in Boosting Hemoglobin Levels and Reducing Incidence of Transfusions

ORLANDO, Fla.--(BUSINESS WIRE)--Dec. 9, 2006--Amgen (NASDAQ: AMGN) today announced data from two studies showing that extended dosing of Aranesp(R) (darbepoetin alfa) is effective in increasing hemoglobin levels to the target level of 11 to 12 g/dL and reducing the need for red blood cell transfusions in patients with chemotherapy-induced anemia. These data were presented at the American Society of Hematology (ASH) 48th Annual Meeting in Orlando, Fla. (Abstracts # 1306, 1552)

"Clinical evidence has demonstrated that extended dosing of Aranesp effectively treats chemotherapy-induced anemia, offering patients a way to synchronize anemia treatment with their chemotherapy and reduce the frequency of injections," said study investigator Johan Vansteenkiste, M.D., Ph.D., Respiratory Oncology Unit, University Hospital Gasthuisberg, Leuven, Belgium. "Our study suggests that the use of Aranesp administered every three weeks in combination with IV iron may improve anemia management, including reaching hemoglobin targets and reducing transfusion requirements, among chemotherapy-induced anemia patients."

Results from a Phase 3b study of 396 patients demonstrated that significantly more patients receiving 500 mcg Aranesp administered every three weeks in combination with IV iron achieved a hematopoietic response (hemoglobin equal or greater than 12 g/dL) compared to patients receiving Aranesp 500 mcg administered every three weeks in combination with standard iron administration (oral iron or no iron) (86 percent (n=200) vs. 73 percent (n=196)).

Further, fewer patients in the Aranesp plus IV iron group received a red blood cell transfusion between week five and the end of treatment compared to patients in the Aranesp plus standard iron administration group (9 percent (n=185) vs. 20 percent (n=190)).

In addition, the results from this trial demonstrated that among patients receiving 500 mcg Aranesp administered every three weeks in combination with IV iron (n=185), 94 percent achieved the target hemoglobin level of greater than or equal to 11 g/dL between week one and the end of the treatment. In the group that received Aranesp and iron administered according to standard practice (oral iron or no iron) (n=190), 85 percent of patients achieved the target hemoglobin level.

About the Phase 3b Study

This randomized, multicenter, open-label, 16-week study of 398 patients with chemotherapy-induced anemia was designed to evaluate the safety and efficacy of 500 mcg Aranesp administered every three weeks with either IV iron (200 mcg administered every three weeks on the same schedule as Aranesp or, if required, as two doses (200 mcg total) within a three-week period) or iron administered according to standard practice. Study endpoints included changes in hemoglobin level from baseline, incidence of transfusions and incidence of adverse events and serious adverse events, in particular thromboembolic events.

Phase 2 Results

In a Phase 2 study, interim data suggest that Aranesp administered every two or three weeks (300 or 500 mcg, respectively) for cancer patients with chemotherapy-induced anemia is at least as effective as weekly administration (150 mcg) in increasing patient hemoglobin levels. Results from 752 patients demonstrated that 74 percent of patients receiving treatment every two or three weeks (n=378) achieved the recommended target hemoglobin level of greater than or equal to 11 g/dL at week 13, the primary endpoint, compared to 76 percent of patients receiving weekly dosing (n=374).

About the Phase 2 Study

This ongoing, randomized, multicenter, open-label, 25-week study of 752 patients was designed to compare the efficacy of Aranesp administered every two or three weeks with weekly administration in patients with chemotherapy-induced anemia. Patients were randomized to receive either the extended dosing schedule (300 mcg every two weeks or 500 mcg every three weeks) or weekly administration (150 mcg) of Aranesp. The primary endpoint was change in hemoglobin level from baseline. Secondary endpoints included incidence of transfusions, changes in patient-reported outcomes, and incidence of adverse events and serious adverse events.

In both studies, the number and type of adverse events were consistent with those previously observed in chemotherapy-induced anemia patients receiving Aranesp. The safety profile for patients receiving Aranesp administered with IV iron appeared to be comparable to patients receiving Aranesp administered with either oral iron or no iron. In the Phase 3b study, treatment-related serious adverse events were similar between the two groups (2 percent in both groups). Cardiovascular and thromboembolic adverse events were reported in few patients (10 percent of patients in the IV iron group and 13 percent of patients in the oral or no iron group) and were not associated with increases in hemoglobin levels. In the Phase 2 study, the safety profiles for patients receiving weekly dosing and extended dosing of Aranesp were similar. Out of 752 recruited patients, one treatment-related thromboembolic adverse event occurred in the extended dosing group (n=378), whereas in the once-weekly group (n=374) none of these adverse events occurred.

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, with 500,000 of those anemic patients having a hemoglobin measurement below 11 g/dL. Approximately 63 percent of European chemotherapy patients will develop anemia as a result of their treatment. 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 target level of 11 to 12 g/dL recommended in the National Comprehensive Cancer Network(R) (NCCN) and the European Organisation for Research on Treatment of Cancer (EORTC) evidence-based 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 2002, Aranesp was approved for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies in the U.S. and European Union (EU). Today, Aranesp is the only erythropoiesis-stimulating protein approved in the U.S. and EU for weekly and every-three-week administration, which allows physicians to synchronize anemia treatment with the majority of chemotherapy schedules. 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 deep and broad 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.

CONTACT: Amgen, Thousand Oaks
Ashleigh Koss, 805-313-6151 (media)
Arvind Sood, 805-447-1060 (investors)

SOURCE: Amgen Inc.