FDA Approves Amgen's Aranesp For Anemia Associated With Chemotherapy

July 22, 2002

THOUSAND OAKS, CA, July 22, 2002 -- Amgen (NASDAQ:AMGN), the world's largest biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has approved Aranesp (darbepoetin alfa) for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies. Aranesp is a recombinant erythropoietic protein (proteins that stimulate production of oxygen-carrying red blood cells) that requires fewer injections than existing treatment.

Amgen revolutionized anemia treatment with the discovery of recombinant human erythropoietin in 1984, which led to the development of Epoetin alfa, currently marketed as EPOGENi and Procritii. Building on this heritage, Amgen created Aranesp, which was developed to simplify anemia management.

Aranesp maintains its level in the blood approximately three times longer than Epoetin alfa, offering healthcare providers the ability to treat anemia related to chemotherapy with less-frequent dosing than the current standard of care.

Less-frequent dosing results in fewer injections for patients. It allows patients and caregivers to spend less time scheduling injection visits, and will free up physicians and nurses to attend to other patients and work activity.

"Anemia can take a tremendous toll on patients undergoing chemotherapy, often leaving them too weak to perform routine activities. In severe cases, anemia can force doctors to interrupt chemotherapy regimens," said Robert E. Smith, Jr., M.D., president of South Carolina Oncology Associates PA and an Aranesp investigator. "Aranesp not only helps correct anemia and maintain hemoglobin levels during chemotherapy, but also helps chemotherapy patients and their physicians overcome barriers that can hinder the delivery of current anemia treatment, notably the need for frequent office visits."

This year, an estimated 1.2 million cancer patients will undergo cytotoxic chemotherapy in the United States; and approximately 800,000 (67%) will become anemic. Anemia is the shortage of oxygen-carrying red blood cells that fuel body function. Patients undergoing chemotherapy often suffer from anemia because chemotherapy not only attacks cancerous cells, but other cells in the body as well, including red blood cells. Aranesp stimulates the bone marrow to increase the production of red blood cells and has been shown to result in a clinically significant improvement of anemia associated with chemotherapy. Before Aranesp, physicians were limited to treating anemia associated with chemotherapy with frequent injections of Epoetin alfa or red blood cell transfusions.

"Aranesp is an important development that will make it easier for oncologists to treat their chemotherapy patients' anemia," said Amgen chairman and chief executive officer Kevin Sharer. "Joining the once-per-chemotherapy-cycle dosed Neulasta (pegfilgrastim), Aranesp's simplified dosing regimen represents Amgen's next generation of powerful supportive care treatments for patients receiving chemotherapy. With Aranesp and Neulasta, Amgen is helping physicians, nurses and patients address two of the most serious complications of chemotherapy."

Clinical studies showed that patients suffering from chemotherapy-related anemia who received Aranesp consistently reached target hemoglobin (red blood cell) levels. The studies showed Aranesp to be generally well-tolerated.

Aranesp was approved by the FDA in September 2001 for the treatment of anemia associated with chronic renal failure, also known as chronic kidney disease, for patients on dialysis and patients not on dialysis.

Aranesp is contraindicated in patients with uncontrolled hypertension. 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; no important differences were observed between Aranesp and Epoetin alfa.

Neulasta was approved by the FDA in January 2002 for decreasing the incidence of infection as manifested by febrile neutropenia (neutropenia with fever) in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs.

In clinical trials, the most common adverse event attributed to Neulasta therapy following combination chemotherapy in patients (n=465) with lymphoma and solid tumors was bone pain, reported in 26% of patients. The only serious adverse event not attributed to underlying disease or chemotherapy was a case of hypoxia. While not reported in patients receiving Neulasta, rare events of adult respiratory distress syndrome, splenic rupture, and sickle cell crisis have been reported in patients receiving the parent compound, Filgrastim.

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent Form 10-Q. Amgen conducts research in the biotechnology/pharmaceutical field where movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product.

Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. In addition, sales of our products are affected by reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers. These government regulations and reimbursement policies may affect the development, usage and pricing of our products.

In addition, while Amgen routinely obtains patents for our products and technology, the protection offered by Amgen patents and patent applications may be challenged, invalidated or circumvented by our competitors.

Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Amgen. Amgen is providing this information as of July 22, 2002 and expressly disclaims any duty to update information contained in this press release.

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