



Aranesp Studies Explore Potential Of New Anemia Treatment Paradigms

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ORLANDO, FL, May 21, 2002 - Clinical data from four Aranesp (darbepoetin alfa) studies presented at the 38th annual meeting of the American Society of Clinical Oncology (ASCO) suggest new potential dosing approaches for treating anemia in patients with cancer. The loading dose paradigm study of Aranesp was shown to improve anemia faster in patients receiving chemotherapy compared to Procrit(R) (Epoetin alfa). Other studies examined the ability of Aranesp to be administered once per cycle of chemotherapy and once per month in anemic patients not receiving chemotherapy.

A 12-week head-to-head study of Aranesp compared to Procrit involving 122 patients led by John Glaspy, MD, MPH, University of California, Los Angeles, was presented at the meeting. Anemic patients on chemotherapy were randomized to receive Aranesp in a four-week front load phase followed by an eight-week Aranesp maintenance phase that involved less frequent dosing or Procrit given 40,000 units per week, as a starting dose. At four weeks, the results show the change in hemoglobin (>2 g/dL hemoglobin increase from baseline) achieved by patients receiving Aranesp was 80 percent greater than achieved by patients receiving Procrit.

After 12 weeks of treatment, the data reported that 61 percent of patients treated with Aranesp responded to treatment (>2 g/dL hemoglobin increase from baseline), compared with 49 percent of patients that responded to Procrit therapy, even when Procrit doses were increased to 60,000 units per week for those patients whose initial responses were inadequate. Aranesp doses were not increased for patients who did not respond. [ASCO abstract #1446; Glaspy et al.]

Other studies involving Aranesp presented at ASCO included:

Dose-finding Study of Aranesp Once per Chemotherapy Cycle in Anemic Patients with Solid Tumors

The majority of chemotherapy regimens are administered either once every three or four weeks. Data reported at ASCO from the Kotasek et al. study evaluated the ability of Aranesp to reduce transfusion requirements and to correct anemia in chemotherapy patients when administered either once every three or once every four weeks. [ASCO abstract #1421; Kotasek et al.]

Aranesp Studied in the Correction of Chronic Anemia of Cancer Not Related to Chemotherapy

Data from Smith et al. study evaluated the ability of Aranesp administered once every one, three or four weeks for correction of chronic anemia of cancer not associated with chemotherapy or radiation therapy. As many as 400,000 cancer patients may suffer from chronic anemia of cancer. [ASCO abstract #1465; Smith et al.]

Aranesp is a recombinant erythropoietic protein (a protein that stimulates production of oxygen-carrying red blood cells). Amgen revolutionized anemia treatment with the discovery of recombinant erythropoietin, Epoetin alfa, which is currently marketed as EPOGEN(R) and Procrit(R). Building on this heritage, Amgen discovered Aranesp, which contains two additional sialic acid-containing carbohydrate chains than the Epoetin alfa molecule resulting in more activity than Epoetin alfa with the added benefit of less-frequent administration, while also retaining a similar safety profile.

Aranesp was approved by the U.S. Food and Drug Administration (FDA) in September 2001 for the treatment of anemia related to chronic renal failure (also known as chronic kidney disease) in patients on dialysis and patients not on dialysis. Aranesp requires fewer injections than treatment with epoetin alfa. Aranesp currently is undergoing FDA review for use in the treatment of anemia in cancer patients receiving chemotherapy.

In the nephrology setting, the most commonly reported side effects in Aranesp trials were infection, hypertension, hypotension, myalgia, headache, and diarrhea. Increases in hemoglobin greater than approximately 1.0 g/dL during any 2-week period have been associated with serious side effects. Aranesp is contraindicated in chronic kidney disease patients with uncontrolled hypertension.

Cancer patients commonly suffer from anemia, an abnormally low level of red blood cells, frequently due to either the cancer itself or because the chemotherapy and radiation used in cancer treatment can reduce the body's ability to produce enough red blood cells. It has been reported that anemia may affect 50 percent to 60 percent of cancer patients who receive chemotherapy and as many as 700,000 cancer patients in the U.S. Despite its prevalence and symptoms, which often include severe physical and mental fatigue, only about one-third of anemic cancer patients on chemotherapy receive treatment for their anemia.

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

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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 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.

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 May 21, 2002 and expressly disclaims any duty to update information contained in this press release.

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