

## New Data Suggest Aranesp(R) Benefits Patients Suffering From Anemia of Cancer, Who Are Not Receiving Chemotherapy

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SAN DIEGO, Dec. 6 -- Amgen (Nasdaq: AMGN), the world's largest biotechnology company, today announced interim data from a randomized, multicenter study that evaluates Aranesp (darbepoetin alfa), administered every two weeks in correcting anemia in cancer patients not undergoing chemotherapy, a condition known as anemia of cancer. The results were presented at the American Society of Hematology (ASH) Annual Meeting. [Abstract #1816]

The interim analysis of the study's first 150 anemic cancer patients with a current diagnoses or history of a nonmyeloid malignancy shows that after 12 weeks of Aranesp treatment, the mean change in hemoglobin was 1.9 g/dL for the Aranesp group and 0.2 g/dL in the control group, which received standard care. The baseline hemoglobin was 10.1 and 10.4 g/dL for the Aranesp and control groups, respectively. Patients were randomized to receive either 3 mcg/kg every other week for 21 weeks or to a control group in which there was a 12-week observation period followed by nine weeks of Aranesp. The Kaplan-Meier estimate (95 percent) of hematopoietic response was 81 percent (71, 90) for the Aranesp group and 26 percent (8, 43) for the control group. Further studies will be conducted to confirm these findings.

While anemia, an abnormally low level of red blood cells, is recognized as a common problem in cancer patients receiving chemotherapy, other patients suffer from anemia due to the cancer itself, unrelated to chemotherapy. Approximately 475,000 cancer patients in the U.S. suffer from anemia of cancer, whose common symptoms include physical and mental fatigue.

"Oncologists are beginning to focus not only on chemotherapy-induced anemia, but anemia of cancer as well," said Dr. Veena Charu, Pacific Cancer Medical Center. "Building on the findings of previous studies, we designed this study to examine the efficacy of Aranesp in treating cancer patients with anemia not receiving chemotherapy."

These data were recently evaluated by U.S. Pharmacopea Drug Index (US-PDI) for inclusion in the monograph. They formed the basis for the acceptance of Aranesp administered every two weeks in the treatment of anemia of cancer.

## **About Aranesp**

Aranesp was approved by the U.S. Food and Drug Administration (FDA) in July 2002 for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies. 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 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 in the U.S. by Amgen as EPOGEN(R)(i) and by Ortho Biotech Products, LP, as Procrit(R)(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 with the added benefit of less-frequent administration.

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.

## About Amgen

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

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Aranesp prescribing information can be accessed by calling 800-772-6436 or by logging onto www.aranesp.com .

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- (i) EPOGEN(R) is a registered trademark of Amgen Inc.
- (ii) Procrit(R) is a registered trademark of Ortho Biotech Products, L.P.

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