



## **New Data On Aranesp(R) Dosed Every Other Week In Anemic Chronic Kidney Disease Patients Presented At 35th Annual Meeting Of The American Society Of Nephrology**

November 3, 2002

PHILADELPHIA, PA, November 3, 2002 - Amgen (Nasdaq: AMGN), the world's largest biotechnology company, today announced results from a large study presented at the American Society of Nephrology (ASN) evaluating the effectiveness of Aranesp(R) (darbepoetin alfa) dosed once every other week for correcting anemia in patients with chronic kidney disease (CKD) not on dialysis. In this study, 96 percent of patients receiving Aranesp were able to reach and maintain target hemoglobin levels.

"This large-scale study reinforces previous data that demonstrated Aranesp's power to correct anemia in CKD patients," said Robert D. Toto, MD, University of Texas, Southwestern Medical School, Dallas, TX, one of the study's lead investigators. "New data continue to demonstrate Aranesp offers physicians and patients a more simplified dosing schedule than existing therapies."

In the study, 608 CKD patients not receiving dialysis received Aranesp once every other week. Of the 463 patients who completed the 24-week study, 445 patients (96.1 percent) reached study target hemoglobin levels (11.0-13.0 g/dL). The average time to achieve hemoglobin response was 5.7 weeks. Adverse events were consistent with those expected in CKD patients receiving erythropoietic therapy. [ASN Abstract # 809; Toto et al.]

### **Aranesp Improves Health-Related Quality of Life in Patients with CKD**

A second study presented at ASN found that treatment of anemia with Aranesp is associated with improvements in health-related quality of life (HRQOL) in patients with CKD. The study, led by Ravi Thadhani, MD, MPH, Massachusetts General Hospital, Boston, MA, examined the change in HRQOL after treatment of anemia with Aranesp. In the 48 patients who completed the study, patients' questionnaire scores increased after receiving treatment with Aranesp.

"We know that Aranesp is effective in raising hemoglobin levels in CKD patients. This study demonstrates that an increase in hemoglobin level translates into improved quality of life for patients," said Dr. Thadhani. "The magnitude of the observed improvements in quality of life is clinically meaningful and shows the value of anemia treatment for CKD patients and its impact on their lives."

### **About Aranesp**

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, the first recombinant EPO product is currently marketed as EPOGEN(R)<sup>i</sup> and Procrit(R)<sup>ii</sup>. Building on this heritage, Amgen designed Aranesp, which contains two additional sialic acid-containing carbohydrate chains compared with Epoetin alfa, resulting in an approximately three fold longer half-life which affords the benefit of extended dosing intervals. Aranesp requires fewer injections than treatment with Epoetin alfa.

Aranesp was approved by the US Food and Drug Administration (FDA) in September 2001 for the treatment of anemia related to chronic renal failure (often referred to as chronic kidney disease) in patients on dialysis and patients not on dialysis. It is also approved for this indication in most European countries, Australia, New Zealand and Canada. Aranesp was also approved in the US (July 2002) and European Union (August 2002) for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies.

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. The individual dose of Aranesp should be adjusted for each patient to achieve and maintain a target hemoglobin not to exceed 12 g/dL. Aranesp is contraindicated in CKD patients with uncontrolled hypertension.

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

###

CONTACT: Amgen, Thousand Oaks  
Michael Beckerich, 805/447-8925 (media)  
Cary Rosansky, 805/447-4634 (investors)

Note: Copies of the study abstracts are available upon request. Full prescribing information is available on the Web for Aranesp at [www.aranesp.com](http://www.aranesp.com).

EDITOR'S NOTE: An electronic version of this news release may be accessed via our web site at <http://www.amgen.com>. Visit the Corporate Center and click on Amgen News. 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 Amgen News section of the web site.

i EPOGEN(R) is a registered trademark of Amgen Inc.

ii Procrit(R) is a registered trademark of Ortho Biotech Products, L.P.