



## Aranesp Approved for Extended Dosing by European Commission

September 21, 2004

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Sept. 20, 2004--

New Dosing Paradigm To Benefit Patients Across EU  
Suffering From Anemia Associated With Cancer Chemotherapy  
and Chronic Kidney Disease

Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that the European Commission has approved expanded marketing authorization for Aranesp(R) (darbepoetin alfa) in the European Union (EU) following the positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) on July 29, 2004. This decision allows extended Aranesp dosing intervals of once-every-three-weeks in the treatment of anemia in adult cancer patients with non-myeloid malignancies who are receiving chemotherapy and up to once-per-month Aranesp administration in the treatment of anemia in chronic kidney disease (CKD) patients not on dialysis.

"This is an important advance for patients, healthcare providers and caregivers across the EU," said Professor Carsten Bokemeyer, Department of Hematology, Oncology and Immunology, Tuebingen University Hospital, Germany. "Aranesp has a unique pharmacokinetic profile compared to conventional rHu-EPO molecules, which means it can be administered less frequently than other erythropoietins. Extended dosing allows healthcare providers to administer Aranesp to adult cancer patients on chemotherapy just once-every-three-weeks, simplifying the treatment process and providing patients the protection they need to manage their anemia."

"Extended dosing makes anemia management in CKD much more convenient," said Fernando Carrera, MD, Eurodial Dialysis Clinic, Leiria, Portugal. "Patients with progressive renal failure often visit their physicians on a monthly basis. Now, the monthly administration of Aranesp can be coordinated with these visits, simplifying anemia management therapy effectively to maximize patient benefits."

Anemia is a common and serious side effect of CKD and cancer chemotherapy. Anemia management with other erythropoietic therapies requires patients to receive treatment more frequently than with Aranesp. As well as consuming the resources of healthcare systems and professionals, this puts a strain on patients themselves who must cope with already demanding treatment regimens. Today's European Commission decision should greatly relieve these burdens.

"Aranesp is the most commonly prescribed erythropoietic treatment for anemia in the EU, and is the first and only erythropoietin approved for every three or four week dosing," said Beth Seidenberg, senior vice president of development and chief medical officer at Amgen. "Patients with grievous illnesses can spend less time in the physicians' office with these new dosing options."

Aranesp was granted marketing authorization by the European Commission in 2001 for the treatment of anemia associated with chronic renal failure in adults and pediatric subjects 11 years of age or older. In 2002, the European Commission approved Aranesp for the treatment of anemia in adult cancer patients receiving chemotherapy with solid tumors. This patient population was subsequently expanded in 2003 to include all adult cancer patients with non-myeloid malignancies receiving chemotherapy.

### Important Information About Aranesp

Aranesp is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic and other serious events; regional guidelines should be referred to for target and maximum hemoglobin levels, and dose adjustment rules should be performed in line with regional prescribing information.

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, also known as CKD, for patients on dialysis and patients not on dialysis. In July 2002, Aranesp was approved by the FDA for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies.

### 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.

### 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, 2003, 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 we project. 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 us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. We develop 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 we may have believed at the time of entering into such relationship. Also, we or others could identify side effects or manufacturing problems with our products after they are on the market. In addition, sales of our 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 US legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our 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 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 and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, the discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our 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 U.S. Food and Drug Administration (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.

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SOURCE: Amgen Inc.