



## **Aranesp(R) (darbepoetin alfa) Approved for Use in All European Paediatric Patients with Chronic Renal Failure Anaemia**

September 28, 2007

### **European Commission Expands Aranesp Indication to Include All Paediatric Patients**

ZUG, Switzerland (Sept. 28, 2007) - Amgen (Europe) GmbH today announced that the European Commission has approved Aranesp(R) (darbepoetin alfa) for the treatment of anaemia associated with chronic renal failure (CRF), also known as chronic kidney disease (CKD), in all European paediatric patients on dialysis or not on dialysis. For patients with CRF, Aranesp was previously indicated for the treatment of adults and only children >11 years of age.

"Consistent with Amgen's ongoing commitment to improving the lives of patients with chronic renal failure and anaemia, we are delighted that the European Commission has approved expanding Aranesp's indication to now include adult and all paediatric patients," said Willard Dere, M.D., senior vice president and international chief medical officer, Amgen. "Based on new data that Amgen submitted, the expanded indication is a positive demonstration of Aranesp's longstanding favorable safety and efficacy profile in CRF patients."

Aranesp prescribing guidance is given separately for adult and paediatric patients in the updated approved Summary of Product Characteristics (SmPC). Treatment for paediatric patients younger than one year of age has not been studied. Since its introduction in 2001, Aranesp has been used in over 2.7 million patients across both its nephrology and oncology indications.

### **About CKD Anaemia**

According to recent research, 10 percent of Europeans suffer from CKD, with many more at an elevated risk for kidney disease. CKD is a progressive and irreversible condition characterised by kidney damage and impaired kidney function. One of the most common symptoms of CKD is anaemia, which is often under-recognised and under-treated. Anaemia occurs when failing kidneys no longer produce enough erythropoietin, resulting in reduced red blood cell production and haemoglobin levels. Anaemia can have a major impact on a patient's health and quality of life. Symptoms include fatigue, weakness, shortness of breath, difficulty concentrating or confusion, dizziness or fainting, pale skin, rapid heartbeat and feeling unusually cold.

### **About Aranesp**

Aranesp was granted marketing authorization by the European Commission in 2001 for the treatment of anaemia associated with chronic renal failure (CRF), in adults and paediatric subjects 11 years of age or older. In 2002, the European Commission approved Aranesp for the treatment of anaemia in adult cancer patients receiving chemotherapy with solid tumours. This patient population was subsequently expanded in 2003 to include treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. Approval was granted in 2004 for extended dosing intervals of once-every-three-weeks in the treatment of anaemia in adult cancer patients with non-myeloid malignancies who are receiving chemotherapy and up to once-per-month Aranesp administration in the treatment of anaemia in chronic kidney disease (CKD) patients not on dialysis. In 2006, the Aranesp label was updated to allow CKD patients on dialysis to switch from rHuEPO one to three times a week to Aranesp every two weeks. In 2007, the Aranesp label was updated to allow for treatment of anaemia associated with CRF, in all European paediatric patients on dialysis or not on dialysis.

Aranesp was approved by the U.S. Food and Drug Administration (FDA) in September 2001 for the treatment of anaemia associated with CRF for patients on dialysis and patients not on dialysis. In July 2002, the FDA approved weekly dosing of Aranesp for the treatment of anaemia caused by concomitantly administered chemotherapy in patients with non-myeloid malignancies and in March 2006, the FDA approved every-three-week dosing in these patients.

### **Important EU Aranesp Safety Information**

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.

The most commonly reported side effects in clinical trials were arthralgia, edema, injection site pain, and thromboembolic event reactions. Prescribers are recommended to consult regional prescribing information before prescribing Aranesp, including side-effects, precautions and contra-indications.

### **Important U.S. Aranesp Safety Information**

**Use the lowest dose of Aranesp(R) that will gradually increase the haemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion.**

**Aranesp(R) and other erythropoiesis-stimulating agents (ESAs) increased the risk for death and for serious cardiovascular events when administered to target a haemoglobin of greater than 12 g/dL**

#### **Cancer Patients: Use of ESAs**

- **Shortened the time to tumour progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target a haemoglobin of greater than 12 g/dL,**
- **Shortened overall survival and increased deaths attributed to disease progression at 4 months in patients with metastatic breast cancer receiving chemotherapy when administered to target a haemoglobin of greater than 12 g/dL,**

- **Increased the risk of death when administered to target a haemoglobin of 12 g/dL in patients with active malignant disease receiving neither chemotherapy or radiation therapy. ESAs are not indicated for this population.**

**Patients receiving ESAs pre-operatively for reduction of allogeneic red blood cell transfusions: A higher incidence of deep venous thrombosis was documented in patients receiving Epoetin alfa who were not receiving prophylactic anticoagulation. Aranesp(R) is not approved for this indication.**

Aranesp is contraindicated in patients with uncontrolled hypertension.

### **About Amgen**

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit [www.amgen.com](http://www.amgen.com).

### **Forward-Looking Statement**

This news release contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Sept. 25, 2007, and expressly disclaims any duty to update information contained in this news release.

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 safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products are affected by the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and health care cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' 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 we 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) or European Medicines Agency (EMA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA, EMA or comparable regulatory body 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 FDA or EMA 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, EMA or comparable regulatory body can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the applicable FDA- or EMA-approved labeling for the products, and not the information discussed in this news release.

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