



## Amgen Announces Update To U.S. Prescribing Information for Aranesp(R) and EPOGEN(R)

March 9, 2007

### New Boxed Warning Applies to Oncology and Nephrology Indications for the Class of Approved ESAs

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--March 9, 2007--Amgen (NASDAQ:AMGN) today announced the U.S. Food and Drug Administration (FDA) has approved updated safety information, including a boxed warning in the prescribing information for the class of drugs known as Erythropoiesis-stimulating Agents (ESAs), including Aranesp(R) (darbepoetin alfa) and EPOGEN(R) (Epoetin alfa).

"Patient safety is unquestionably our top priority. Amgen is committed to providing timely and appropriate communications to physicians and patients whenever we become aware of new safety information that could affect clinical practice," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen.

Updated information for patients in the revised label notes that "patients should be informed of the increased risks of mortality, serious cardiovascular events, thromboembolic events, and tumor progression when used in off-label dose regimens or populations."

The new boxed warning notes that ESAs, when administered to target a hemoglobin of greater than 12 g/dL:

- Increased the risk for death and for serious cardiovascular events;
- Shortened the time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy; and
- Shortened overall survival and increased deaths attributed to disease progression at four months in patients with metastatic breast cancer receiving chemotherapy.

Cardiovascular events and tumor progression have been moved to the "Warnings" section from the "Precautions" section of all ESA labels.

The new boxed warning also states that ESAs increased the risk of death when administered to target a hemoglobin of 12 g/dL in patients with active malignant disease receiving neither chemotherapy nor radiation therapy. ESAs are not indicated for this population. In addition, for patients receiving ESAs pre-operatively for reduction of allogeneic blood transfusions, a higher incidence of deep venous thrombosis was documented in patients receiving Epoetin alfa who were not receiving prophylactic anticoagulation. Aranesp is not approved for this indication.

"The boxed warning includes information from several investigational studies that were previously communicated to the medical community," added Dr. Perlmutter. "The vast majority of oncologists and nephrologists do not appear to be maintaining Hb levels above 12 g/dL in approved indications."

Physicians are advised in the boxed warning and "Dosing and Administration" section to use the lowest dose of ESAs that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions, and not to exceed 12 g/dL. Additional dosing information for cancer patients has been updated in the "Dosage and Administration" section of the prescribing information, including new dosing adjustment and withholding guidelines to keep hemoglobin levels from exceeding 12 g/dL.

Amgen is informing healthcare professionals about the revisions to the U.S. prescribing information through a joint "Dear Healthcare Professional" letter with Ortho Biotech and will post the letter and updated prescribing information on Amgen's Web site, [www.amgen.com](http://www.amgen.com). Amgen is committed to broadly disseminating this important new prescribing information so that prescribers are informed about the safety of ESAs. Over the coming weeks, our field force will be calling on healthcare professionals to communicate this important new safety information.

The FDA is planning to review the safety and efficacy of ESAs at an upcoming meeting of the FDA's Oncologic Drugs Advisory Committee (ODAC) on May 10, 2007. Amgen is fully committed to participating in this expert review of the safety and efficacy of ESAs.

The indications for Aranesp and EPOGEN have not changed. Aranesp is indicated for the treatment of chemotherapy-induced anemia and anemia associated with chronic kidney disease (CKD), for patients on dialysis and patients not on dialysis. EPOGEN is indicated for the treatment of anemia associated with CKD, for patients on dialysis. Amgen always recommends that physicians and other prescribers carefully follow FDA-approved prescribing instructions.

### 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, 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 involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended Dec. 31, 2006 and in our 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. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, sales growth of recently launched

products, difficulties or delays in manufacturing our products and regulatory developments (domestic or foreign) involving current and future products and manufacturing facilities. 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 and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of our products. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify side effects or manufacturing problems with our products after they are on the market. 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. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. 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. Further, some raw materials, medical devices and component parts for our products are supplied by sole third party suppliers.

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**SOURCE: Amgen**