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

March 7, 2008

Revised Boxed Warning Applies to Oncology Indication for the Class of Approved ESAs

THOUSAND OAKS, Calif., Mar 07, 2008 (BUSINESS WIRE) -- Amgen Inc. (NASDAQ:AMGN) today announced the U.S. Food and Drug Administration (FDA) has approved updated safety information, including an updated boxed warning in the labeling information for the class of drugs known as erythropoiesis-stimulating agents (ESAs), including Aranesp(R) (darbepoetin alfa) and EPOGEN(R) (Epoetin alfa).

The updated boxed warning states that ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid and cervical cancers, when dosed to target a hemoglobin of greater than or equal to 12 g/dL.

In the "Increased Mortality and/or Tumor Progression" warning section of the updated labeling, the interim results of the Preoperative Epirubicin Paclitaxel Aranesp (PREPARE) study in neo-adjuvant breast cancer were added as well as follow up data from the Gynecologic Oncology Group study in cervical cancer.

Amgen and Johnson & Johnson have submitted all available clinical data to the FDA including the data from these two study studies now reflected in the product labeling, as well as data from other informative controlled clinical studies with ESAs in the oncology setting. In general, these results have not changed the benefit-risk profile significantly of ESAs in this setting from previously available data discussed at the May 4, 2004, and May 10, 2007, Oncologic Drugs Advisory Committee (ODAC) meetings. Amgen will address the science and safety of ESAs in oncology, including these new data, at an upcoming ODAC meeting next week on Thursday, March 13, 2008.

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 along with the updated prescribing information on Amgen's Web site, www.amgen.com.

"Amgen is committed to ensuring physicians and patients have the latest information about ESAs in order to make appropriate treatment decisions," said Sean Harper, Amgen's Chief Medical Officer. "Last year, we communicated the new safety information in several ways, including disseminating DHCP letters, posting the new labeling on our Web site, focusing promotional activity from March until the May ODAC on warnings and safety data, and hosting ongoing briefings with the oncology community."

Amgen's ongoing risk management activities includes working with the FDA to design additional pharmacovigilance studies to address safety concerns around ESAs, developing a patient medication guide to communicate the benefit/risk of ESAs, and continuing to publicly communicate updates on ESAs to the public and oncology community.

Important Aranesp and EPOGEN Safety Information

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR and THROMBOEMBOLIC EVENTS, and TUMOR PROGRESSION

Renal failure: Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Cancer:

-- ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers when dosed to target a hemoglobin of greater than or equal to 12 g/dL.

-- The risks of shortened survival and tumor progression have not been excluded when ESAs are dosed to target a hemoglobin of less than 12 g/dL.

-- To minimize these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusions.

-- Use only for treatment of anemia due to concomitant myelosuppressive chemotherapy.

-- Discontinue following the completion of a chemotherapy course.

Aranesp is contraindicated in patients with uncontrolled hypertension.

About Amgen

Amgen discovers, develops, manufacturers 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.

Forward-Looking Statements

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, 2007, 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, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign) and difficulties or delays in manufacturing our products. 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 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. 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 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 product liability claims. Further, 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. 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, 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. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers.

SOURCE: Amgen Inc.

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