



Amgen in Discussions with FDA to Update U.S. Prescribing Information for ESAs

December 7, 2007

Revised ESA Labeling to be Based on New Data from PREPARE and GOG Studies

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Dec. 6, 2007--Amgen Inc. (NASDAQ:AMGN) today announced the company is in discussions with the U.S. Food and Drug Administration (FDA) with the goal of updating safety information in all erythropoiesis-stimulating agents (ESAs) labeling based on safety data from the recently announced PREPARE interim study results in neoadjuvant breast cancer and the recently published follow up data from the Gynecologic Oncology Group (GOG) study in cervical cancer. While Amgen's interactions with the FDA are ongoing and exact language for the updated labeling is not final, the company is committed to providing timely and appropriate communications to patients and physicians.

Amgen and the FDA are discussing the label changes under the regulatory mechanism known as a "changes being effected" (CBE) process. Additionally, Amgen has been advised there will be an Oncologic Drugs Advisory Committee (ODAC) meeting in the first quarter of 2008 as part of the ongoing pharmacovigilance review of ESA therapies. Decisions around the precise timing of this ODAC meeting will not be finalized until publication by the FDA in the Federal Register.

"The PREPARE and GOG studies were off-label, high-hemoglobin target studies that contain important information relevant to specific patient populations receiving ESAs," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "As new information, including additional study results, becomes available, Amgen will communicate the data and, where appropriate, work with the FDA to update our product labels."

Additional information about the PREPARE and GOG studies is available at www.amgen.com.

About Aranesp

Aranesp was approved by the FDA in September 2001 for the treatment of anemia associated with chronic renal failure (CRF) for patients on dialysis and patients not on dialysis. In July 2002, the FDA approved weekly dosing of Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with nonmyeloid malignancies and in March 2006, the FDA approved every-three-week dosing in these patients.

Important Aranesp 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 advanced breast, head and neck, lymphoid, and non-small cell lung malignancies 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 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, 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, 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.

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