Amgen to Discuss Benefits and Risks of ESA Treatment for Cancer Patients with Anemia Due to Chemotherapy at FDA ODAC Meeting

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ESAs Provide Important Clinical Benefits to Cancer Patients With Anemia Due to Chemotherapy; Ongoing and Planned Risk Management Will Further Reduce Risks

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--March 13, 2008--Amgen Inc. (NASDAQ: AMGN) will today present the benefits and risks of Erythropoiesis-stimulating Agents (ESAs) in cancer patients with anemia due to concomitantly administered chemotherapy at a meeting with the U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC). ESAs provide these patients with the only therapeutic alternative to red blood cell (RBC) transfusions, which have known and uncertain risks.

"ESAs provide an unequivocal treatment benefit for cancer patients undergoing chemotherapy by reducing the need for blood transfusions," said Roger M. Perlmutter, M.D., Ph.D., executive vice president, of Research and Development at Amgen. "We look forward to discussing with the ODAC a robust risk management program to reduce ESA risks while still providing access and benefits to the appropriate patients."

For a complete review and analysis of Amgen's presentation to the ODAC, Amgen's and FDA's briefing materials for the ODAC meeting are available at www.Amgen.com or www.fda.gov.

Highlights of Amgen's presentation to the ODAC will include the following:

ESA Treatment Benefits

- ESAs provide the only therapeutic alternative to RBC transfusions in cancer patients with anemia due to concomitantly administered chemotherapy.
- In well-controlled clinical trials, ESAs have been proven to reduce RBC transfusions in patients with anemia receiving chemotherapy.
- If ESAs were not available, data from Amgen's placebo-controlled clinical trials suggest that twice as many patients receiving chemotherapy would require RBC transfusions.

Risks of ESAs

- Eight ESA studies have shown safety signals when patients were studied at higher than currently labeled hemoglobin targets and/or for new experimental indications (such as radiotherapy or patients not receiving chemotherapy).
- Six of these eight studies were discussed at ODAC meetings in 2004 and 2007. Since the May 2007 ODAC meeting, new data from two studies have become available, including interim results from the PREPARE (a study in neo-adjuvant breast cancer) and long-term follow up data from GOG-191 (a study in cervical cancer), both of which targeted hemoglobin levels higher than in the current approved product label.
- These safety signals are inconsistently observed across a total of 59 studies.
- The current label notes the hypothetical risks of shortened overall survival and/or tumor progression when hemoglobin targets are less than or equal to 12 g/dL.
- Potential mechanisms for these safety signals may include thromboembolic events which have long been recognized in ESA labeling. Other mechanisms include the recently labeled but unproven hypothesis of tumor progression and reduced efficacy of radiotherapy at high hemoglobin levels.

Amgen will review the totality of clinical evidence with ODAC, including all favorable and unfavorable studies.

"Although these safety signals have been inconsistently observed across a number of ESA studies, Amgen nonetheless takes them very seriously, and is committed to conducting a controlled clinical trial based on the current label to definitively address these issues," said Perlmutter. "Patient safety is our top priority. To this end, we look forward to the ODAC's recommendations on the proposed clinical study and will continue to collaborate with the FDA, NCI and others to address these safety concerns."

Risks of Blood Transfusions

The use of blood transfusions to treat anemia carries several types of known and uncertain risks for patients with cancer and for the public as a whole. Additionally, the benefits of RBC transfusions are transient, requiring some patients to receive multiple transfusions during the duration of their chemotherapy treatment.

- Although the blood supply is currently considered safer than in the past, there are both known and unknown risks associated with transfusions.
- Blood transfusions also can be associated with transfusion reactions or other antibody mediated problems.
- Physicians have stated that transfusions are disruptive for patients, caregivers and physicians and divert substantial resources that would otherwise be available for patient care.

Proposed Risk Management Program to Preserve Access and Minimize Risks

Additional risk management, through additional product labeling updates and a formal education and communication program, will minimize risk while the necessary data are acquired from clinical trials designed to address the unanswered safety questions. Amgen will propose to the ODAC a risk program that is designed to minimize the risks of ESA therapy, discourage off-label use, and promote educated benefit-risk decisions for each patient.

About Aranesp

Aranesp(R) (darbepoetin alfa) 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.

About EPOGEN

Amgen launched EPOGEN(R) (Epoetin alfa), one of the first biologically derived human therapeutics, into the U.S. medical marketplace in 1989 for the treatment of anemia in patients with chronic renal failure on dialysis. EPOGEN is a recombinant protein with the same mechanism of action as endogenous human erythropoietin, a protein produced by the kidneys to stimulate the production of oxygen-transporting red blood cells.

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.

Perisurgery: EPOGEN(R) increased the rate of deep venous thromboses in patients not receiving prophylactic anticoagulation. Consider deep venous thrombosis prophylaxis.

Aranesp and EPOGEN are contraindicated in patients with uncontrolled hypertension.

About Amgen

Amgen discovers, develops, manufactures 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 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 March 13, 2008 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 healthcare 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 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 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