Amgen to Review Benefits, Risks of ESA Therapy in Chronic Renal Failure Patients at FDA Advisory Committee

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Company Recommends Hemoglobin Target of 10-12 g/dL as Risk Management Approach

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Sept. 11, 2007--Amgen (NASDAQ:AMGN) is presenting data today on the appropriate use of Erythropoiesis Stimulating Agents (ESAs) in Chronic Renal Failure (CRF) patients to a joint meeting of U.S. Food and Drug Administration (FDA) advisory committees.

Amgen's presentation reviews data demonstrating that ESAs are safe when used appropriately and explains the critical role ESAs play in managing the debilitating effects of anemia in CRF patients. The company's presentation recognizes the potential risks observed in recent experimental trials targeting higher-than-recommended hemoglobin levels, lays out the need for an appropriate hemoglobin target of 10-12 g/dL to guide treatment and manage risk, and highlights the importance of the ongoing Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT) to provide answers on the impact of anemia treatment in CRF patients. The company also identifies areas for future study and presents data that suggests that patient response is a stronger risk factor for poor outcomes than ESA dose.

"ESA treatment changed the lives of CRF patients by filling an unmet medical need for a very sick population of dialysis patients," said Allen R. Nissenson, M.D., professor of medicine, associate dean, and director of the Dialysis Program at the University of California, Los Angeles (UCLA). "ESA treatment reduced the need for potentially problematic blood transfusions and improved patient exercise ability, physical functions and symptoms of anemia. As we continue evaluating the appropriate use of ESA therapy, it's vital to remember the patients. It's hard to overstate how sick these patients are and how vulnerable they can be to changes in treatment."

Amgen's ESA products Aranesp(R) (darbepoetin alfa) and EPOGEN(R) (Epoetin alfa) have been used in more than 2.2 million CRF patients.

Target Hemoglobin Range

"Physicians tell us that to optimally treat anemia in CRF patients they need a hemoglobin target range to guide ESA dosing decisions," said Preston Klassen, M.D., executive director, Clinical Development, Amgen. "In response to recent safety signals, Amgen is proposing a conservative hemoglobin target range of 10 to 12 g/dL based on clinical trial data, dialysis population surveillance data and nearly two decades of clinical experience."

In the 1980's, double-blind, randomized, placebo-controlled registrational clinical trials targeting a hemoglobin range between 10.7-12.7 g/dL showed that use of EPOGEN virtually eliminated the need for blood transfusions in dialysis patients. Amgen will discuss with the advisory committee data from these randomized clinical trials that also shows the impact of EPOGEN on improving exercise capacity and patient-reported outcomes.

A hemoglobin target range of 10-12 g/dL was included in the product labeling for EPOGEN from 1992 to 2007. In March 2007, following the publication of clinical trial results that highlighted safety concerns when ESAs are used to target hemoglobin levels of greater than 13 g/dL, the FDA and Amgen announced the addition of a black box safety warning to all ESA labels. The concept of a hemoglobin target range was removed from ESA labeling at this time.

In response to new data the National Kidney Foundation conducted a comprehensive review of all ESA clinical trials in CRF and in August 2007 updated its clinical practice guidelines for Anemia Management to state that "the selected hemoglobin target should generally be in the range 11 to 12 g/dL."

Recent Emphasis on Poorly Responsive Patients

Recent analyses of previous clinical trials has led to a focus on a subset of CRF patients whose changing health status results in transient periods of poor responsiveness to ESA therapy. In clinical trials, worse outcomes have been reported in this subset of patients, who are often described as "hyporesponders."

Poor responders appear to have a greater underlying burden of illness resulting in greater risk of mortality. ESA responsiveness reflects underlying health status and is a better predictor of clinical risk than ESA dose alone.

"Amgen welcomes discussion with FDA on potential study designs to explore approaches to dosing that will provide optimal anemia management in this subset of very ill patients," explained Dr. Klassen.

Questions about higher doses

Some analyses have shown that higher ESA doses are associated with poor outcomes. However, Amgen noted that it is difficult to determine if higher doses cause worse outcomes, or if higher doses are observed in patients who are poor responders because of worse health status.

"Generally patients with poor ESA responsiveness and who receive the highest ESA doses have very poor health status and suffer from multiple co-morbid illnesses," said Dr. Klassen. "It would be expected that these patients would have worse clinical outcomes."

Amgen will discuss with the FDA potential study designs to further explore optimal anemia management in these patients.

TREAT Study

Amgen will provide an update on the ongoing TREAT trial that will investigate important questions about the potential survival advantages of ESA therapy in CRF patients. TREAT is a 4,000-patient, global multi-center, randomized, double-blind, placebo-controlled trial to determine the impact of anemia therapy on mortality and cardiovascular morbidity in patients with CKD and type 2 diabetes.

Briefing Materials

Amgen's full presentation and briefing materials submitted to the joint meeting of the Cardiovascular and Renal Drugs Advisory (CRDAC) and Drug Safety and Risk Management Advisory (DSRM) Committees are available at www.amgen.com.

About EPOGEN

Amgen launched EPOGEN(R), 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.

About Aranesp

Aranesp(R) was approved by the U.S. Food and Drug Administration (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 Safety Information Including Boxed WARNINGS

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

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

Cancer Patients: Use of ESAs:

- shortened the time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target a hemoglobin 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 hemoglobin of greater than 12 g/dL;
- 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.

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. Antithrombotic prophylaxis should be strongly considered when Epoetin alfa is used to reduce allogeneic red blood cell transfusions. Aranesp(R) is not approved for this indication.

Aranesp and EPOGEN are 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 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 Amgen's Form 10-K for the year ended Dec. 31, 2006, and in Amgen's 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), 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. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. 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. 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 and Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of Amgen's existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of Amgen's products or product candidates. Further, the discovery of significant problems with a product similar to one

of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers.

Aranesp prescribing information can be accessed by calling 800-772-6436 or by logging on to www.aranesp.com.

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