Amgen to Review Results From TREAT and Propose Updates to ESA Labeling for Chronic Renal Failure Patients at an FDA Advisory Committee Meeting Today

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Amgen (Nasdaq: AMGN) will review the results from TREAT (the Trial to Reduce Cardiovascular Events with Aranesp(R) Therapy) and will discuss how these results inform the appropriate use of erythropoiesis-stimulating agents (ESAs) for chronic renal failure (CRF) patients at today's meeting of the Food and Drug Administration's (FDA) Cardiovascular and Renal Drugs Advisory Committee (CRDAC).

"This advisory committee meeting is a valuable forum for the FDA, Amgen and the nephrology community to review the results from TREAT, which further inform use of ESAs in patients with chronic renal failure who are not on dialysis," said Reshma Kewalramani, M.D., FASN, executive director, Global Development at Amgen. "We look forward to sharing our analyses of TREAT and describing proposed label changes that will help guide nephrologists in focusing their use of ESA therapy on patients most likely to benefit."

TREAT, the largest study of ESA use in CRF patients to date, is a randomized, double-blind, placebo-controlled, Phase 3 study of patients with moderate kidney dysfunction who were not on dialysis, had moderate anemia and type-2 diabetes and were treated to a hemoglobin target of 13 g/dL, a higher level than recommended in the current approved ESA label. The study did not meet its endpoints of demonstrating a reduction in all-cause mortality, cardiovascular morbidity or end-stage renal disease and showed an increased risk of stroke in the Aranesp (darbepoetin alfa) arm, among other key findings.

The results from TREAT provide important information about the cardiovascular risks of treating CRF patients with ESAs to a hemoglobin target of 13 g/dL or greater. Cardiovascular risks have been reflected in the boxed warning of the FDA-approved ESA labels since 2007 and, in December 2009, Amgen further strengthened the warnings to incorporate the specific stroke risk found in TREAT.

Amgen is proposing changes to the ESA labels that would limit treatment to patients who are most likely to benefit, specifically those with significant anemia (<10 g/dL), and who are at high risk for transfusion and for whom transfusion avoidance is considered clinically important, including those in whom it is important to preserve kidney transplant eligibility. In addition to narrowing the patient population, Amgen is proposing a more conservative dosing algorithm in these patients. For CRF patients receiving dialysis - a population not studied in TREAT - the benefits demonstrated in registration clinical trials and supported by years of clinical practice experience are clear and remain unchanged.

"The nephrology community has, and will continue to gain, significant understanding about the treatment of anemia in patients with chronic kidney disease not on dialysis from this large and rigorously designed and conducted clinical trial," stated Robert Toto, M.D., University of Texas Southwestern Medical Center. "First and foremost, TREAT has informed us that the risks of treatment may outweigh the benefits for some patients with chronic kidney disease and anemia who are not on dialysis. However, ESAs remain an important therapeutic option for patients on dialysis, where the benefits are clear, and for certain patients not on dialysis; specifically those with significant anemia in whom blood transfusion avoidance is important, especially to preserve eligibility for kidney transplantation, the preferred treatment option for patients with failing kidneys."

TREAT Study Design and Key Findings

TREAT enrolled 4,038 patients not on dialysis with type-2 diabetes and moderate anemia. Designed as a superiority study to demonstrate improved cardiovascular outcomes, patients enrolled in the study were randomized in a one-to-one ratio to receive either treatment with Aranesp to a target hemoglobin of 13 g/dL or placebo. Due to the increased risk of negative outcomes associated with low hemoglobin levels, patients in the control arm whose hemoglobin fell below 9 g/dL were given Aranesp as a rescue medication until their hemoglobin level reached 9 g/dL. Investigators were blinded to this intervention.

The key findings from TREAT include:

- The study failed to meet either of its primary endpoints of:
  - improving mortality and CV morbidity or
  - extending time to death or ESRD
- TREAT showed:
  - An almost 2-fold increased risk of stroke (HR = 1.92 [95 percent CI: 1.38-2.68], annualized incidence rate 2.1 percent vs. 1.1 percent) in the Aranesp arm
  - Among patients with history of malignancy, a higher number of deaths due to any cause and of death adjudicated as due to malignancy in the Aranesp arm
  - Aranesp therapy significantly reduced the need for transfusions
  - A statistically-significant but clinically modest improvement in patient-reported outcomes for patients in the Aranesp arm

Chronic Kidney Disease: Impact and Prevalence

CKD affects more than 26 million Americans and millions more worldwide. The disease is characterized by progressive kidney damage and impaired kidney function and is most often caused by type-2 diabetes or high blood pressure. When CKD progresses to kidney failure, chronic dialysis or a kidney transplant are required to sustain life. Anemia is a common complication of CKD that may begin in the early stages of the disease and becomes more common and severe as kidney function declines.

About Aranesp

Aranesp was approved by the FDA in 2001 for the treatment of anemia associated with CRF for patients on dialysis and patients not on dialysis. The European Commission granted marketing authorization for the same indication in 2001 and subsequently updated it for CRF patients with symptomatic anemia in 2008.

In 2002, the FDA approved Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with nonmyeloid malignancies. The European Commission authorized the treatment of anemia caused by concomitantly administered chemotherapy in patients with non-haematological malignancies in 2002 and extended it to include non-myeloid malignancies in patients receiving chemotherapy in 2003.

Important Safety Information, including Boxed WARNINGS:

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR EVENTS, THROMBOEMBOLIC EVENTS, STROKE and INCREASED RISK OF TUMOR PROGRESSION OR RECURRENCE

Chronic Renal Failure:

- In clinical studies, patients experienced greater risks for death, serious cardiovascular events, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target hemoglobin levels of 13 g/dL and above.
- Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Cancer:

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers (see WARNINGS: Table 1).
- To decrease these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusion.
- Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense PROCRIT to patients with cancer. To enroll in the ESA APPRISE Oncology Program, visit www.esa-apprise.com or call 1-866-284-8089 for further assistance.
- Use ESAs only for treatment of anemia due to concomitant myelosuppressive chemotherapy.
- ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure.
- Discontinue following the completion of a chemotherapy course.

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

(See WARNINGS: Increased Mortality, Serious Cardiovascular Events, Thromboembolic Events, and Stroke, WARNINGS: Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence, INDICATIONS AND USAGE, and DOSAGE AND ADMINISTRATION.)

- ESAs 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 Statements

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 Oct. 18, 2010 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 U.S. Food and Drug Administration (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 U.S. 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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