Amgen Announces Modifications to U.S. Prescribing Information for Use of Erythropoiesis-Stimulating Agents in Chronic Kidney Disease

June 24, 2011

Modified Labeling Provides Different Treatment Guidance for Patients on Dialysis and Not on Dialysis
Changes to Prescribing Information Include Modification to the Boxed Warning

THOUSAND OAKS, Calif., June 24, 2011 /PRNewswire via COMTEX/ --

Amgen (NASDAQ: AMGN) announced today that the U.S. Food and Drug Administration (FDA) has approved modified language in the prescribing information for the use of erythropoiesis-stimulating agents (ESAs), including Aranesp® (darbepoetin alfa) and EPOGEN® (Epoetin alfa), in patients with chronic kidney disease (CKD). The modified language, including changes to the Boxed Warning, provides important new information for the treatment of patients with CKD who are on dialysis, as well as those not on dialysis, to inform prescribers and patients of safety risks that have been identified in clinical trials. In recognition of the different benefit-risk profiles of ESA therapy in patients on dialysis compared to patients not on dialysis, the modified labeling provides separate treatment guidance for these two CKD populations.

Specifically, for patients on dialysis, the label advises physicians to initiate ESA therapy when the hemoglobin level is less than 10 g/dL and guides physicians to reduce or interrupt the dose when the hemoglobin approaches or exceeds 11 g/dL. For patients not on dialysis, physicians are asked to consider initiating ESA therapy when the hemoglobin level is below 10 g/dL, when reducing red blood cell transfusion-related risks is a clinical goal and when the rate of hemoglobin decline suggests a transfusion will be likely. Further, for those not on dialysis, physicians should reduce or interrupt the dose when the hemoglobin exceeds 10 g/dL. This guidance replaces the previous label language specifying a hemoglobin target range of 10-12 g/dL for both populations. The modified prescribing information continues to recognize the benefit of reducing the need for transfusions in CKD patients.

In addition, the Boxed Warning, Warnings and Precautions and Clinical Studies sections have been modified to advise that the use of ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions.

For complete dosing and safety information for Aranesp and EPOGEN, see the full prescribing information.

"Amgen supports the modified ESA prescribing information as it informs physicians of important safety information," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "The revised label also provides physicians with more individualized treatment guidance by distinguishing between patients undergoing dialysis as compared with those who are not on dialysis."

The language in the prescribing information was informed by the results from clinical trials, including TREAT (the Trial to Reduce Cardiovascular Events with Aranesp® Therapy), which targeted high hemoglobin levels (13 g/dL) in CKD patients who were not on dialysis and found an increased risk of stroke in the patients treated with ESAs compared to those receiving placebo. While TREAT was a study of patients who were not on dialysis, the modified Boxed Warning and other warnings in the label apply to all CKD patients.

Amgen is informing healthcare professionals about the revisions to the prescribing information through a joint "Dear Healthcare Professional" letter with Janssen Products, LP and will post the letter, along with the modified prescribing information on Amgen's website, www.amgen.com.

Amgen is in ongoing discussions with the FDA regarding additional post-marketing required studies to further understand the benefit-risk profile of ESAs in CKD patients on dialysis and not on dialysis.

About Aranesp and EPOGEN

Aranesp is indicated for the treatment of anemia due to CKD, including patients on dialysis and not on dialysis.

EPOGEN is indicated for the treatment of anemia due to CKD, including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusions.

Aranesp and EPOGEN have not been shown to improve quality of life, fatigue, or patient well-being.

Aranesp and EPOGEN are not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

IMPORTANT SAFETY INFORMATION

WARNING: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE

***Chronic Kidney Disease*:**

- **In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.**
- **No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.**
- **Use the lowest Aranesp or EPOGEN dose sufficient to reduce the need for red blood cell (RBC) transfusions.**

***Cancer*:**

- **ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.**
- **Prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense Aranesp or EPOGEN to patients with cancer.**
- **Use the lowest dose to avoid RBC transfusions.**
- **Use ESAs only for anemia from myelosuppressive chemotherapy.**
- **ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure.**
- **Discontinue following the completion of a chemotherapy course.**

Perisurgery: (EPOGEN)

- **Due to increased risk of deep venous thrombosis (DVT), DVT prophylaxis is recommended.**

- Aranesp and EPOGEN are contraindicated in patients with uncontrolled hypertension; pure red cell aplasia that begins after treatment with Aranesp, EPOGEN, or other erythropoietin protein drugs; or serious allergic reactions to Aranesp or EPOGEN.
- EPOGEN from multidose vials is contraindicated in neonates, infants, pregnant women, and nursing mothers.

For all patients who take Aranesp or EPOGEN, including patients with cancer or chronic kidney disease:

- If you decide to take Aranesp or EPOGEN, your healthcare provider should prescribe the smallest dose of Aranesp or EPOGEN that is needed to reduce your chance of getting red blood cell transfusions.
- You may get serious heart problems such as heart attack, stroke, heart failure, and may die sooner if you are treated with Aranesp or EPOGEN to reach a normal or near-normal hemoglobin level.
- You may get blood clots at any time while taking Aranesp or EPOGEN. If you are receiving Aranesp or EPOGEN for any reason and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus).

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, bone disease 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 June 24, 2011 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.

Contact: Amgen, Thousand Oaks
Christine Regan: (805) 447-5476 (U.S. media)
Arvind Sood: (805) 447-1060 (investors)

(Logo: http://photos.prnewswire.com/prnh/20081015/AMGENLOGO)

SOURCE Amgen