Amgen and Centocor Ortho Biotech Products Finalize ESA Risk Evaluation and Mitigation Strategy (REMS) With FDA

February 16, 2010

--Companies To Launch ESA APPRISE Program On March 24, 2010 For Patients With Cancer
--Medication Guide Available For All Indications

THOUSAND OAKS, Calif., Feb 16, 2010 /PRNewswire via COMTEX/ -- Amgen Inc. (Nasdaq: AMGN) and Centocor Ortho Biotech Products, L.P., today announced that the U.S. Food and Drug Administration (FDA) has approved the Risk Evaluation and Mitigation Strategy (REMS) for erythropoiesis-stimulating agents (ESAs), which include Aranesp(R) (darbepoetin alfa), EPOGEN(R) (Epoetin alfa) and PROCRIT(R) (Epoetin alfa). The FDA has determined that a REMS is necessary for ESAs to ensure the benefits of these drugs outweigh the risks of shortened overall survival and/or increased tumor progression or recurrence as identified in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid and cervical cancers.

As part of the REMS, a Medication Guide explaining the risks and benefits of ESAs must be provided to all patients receiving ESAs. To ensure continued access to ESAs for healthcare providers who prescribe, or prescribe and dispense, ESAs to patients with cancer, providers are required to train and enroll in the ESA APPRISE (**A**ssisting **P**roviders and cancer **P**atients with **R**isk **I**nformation for the **S**afe use of **E**SAs) Oncology Program and to document that a discussion about the risks of ESAs took place with each patient prior to the initiation of each new course of ESA therapy. The ESA APPRISE Oncology Program will be launched on March 24, 2010. Direct patient registration or approval prior to ESA administration is not required through the ESA APPRISE Oncology Program.

The goal of the ESA REMS is to support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Aranesp, EPOGEN or PROCRIT educating them on the risks of ESAs. For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE Oncology Program, is to mitigate the risk of decreased survival and/or poorer tumor outcomes.

"The ESA REMS represents our continued commitment to patient education and safety," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "This program supports a thoughtful dialogue between healthcare providers and patients when considering ESA treatment."

To support the implementation of the ESA APPRISE Oncology Program, Amgen and Centocor Ortho Biotech Products will distribute a Dear Healthcare Provider letter introducing the program, providing the rationale, program objectives, training and enrollment requirements and consequences for non-enrollment. Beginning March 24, healthcare providers who prescribe, or prescribe and dispense ESAs for patients with cancer and hospitals that dispense ESAs for patients with cancer will be able to train and enroll in the ESA APPRISE Oncology Program by contacting their local Amgen or Centocor Ortho Biotech Products field representative or by accessing the ESA APPRISE Oncology Program Website, **www.esa-apprise.com**.

For information about the complete ESA APPRISE Oncology program, please visit http://wwwext.amgen.com/media/amgen_esa_risk_evaluation.html or http://www.centocororthobiotech.com/. For full prescribing information and medication guides, please visit http://www.aranesp.com/, http://www.epogen.com/, and http://www.procrit.com/.

IMPORTANT SAFETY INFORMATION

Aranesp is indicated for the treatment of anemia in patients with most types of cancer receiving chemotherapy as well as in patients with chronic renal failure (CRF), including patients on dialysis and patients not on dialysis.

EPOGEN is indicated for the treatment of anemia in patients with CRF on dialysis. EPOGEN is indicated to elevate or maintain the red blood cell (RBC) level and to decrease the need for transfusions in these patients.

PROCRIT is used for the treatment of anemia in patients with most types of cancer receiving chemotherapy, with chronic renal failure who are on dialysis and those who are not on dialysis, who are being treated with zidovudine for HIV infection, and to reduce the need for transfusion in anemic patients who are scheduled for elective noncardiac, nonvascular surgery. Depending on the country in which Epoetin alfa is marketed, these indications may differ.

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.
- 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 Aranesp, EPOGEN or PROCRIT to patients with cancer. To enroll in the ESA APPRISE Oncology Program, visit http://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 / Procrit increased the rate of deep venous thromboses in patients not receiving prophylactic anticoagulation. Consider deep venous thrombosis prophylaxis.

- ESAs 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 http://www.amgen.com/.

Amgen 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 Feb. 16, 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, 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. 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 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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