Amgen Responds to Final CMS National Coverage Determination on Use of Erythropoiesis-Stimulating Agents in Oncology

August 1, 2007

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--July 31, 2007--Amgen (NASDAQ:AMGN) today announced its response to the Centers for Medicare and Medicaid Services' (CMS) final National Coverage Determination (NCD) on the use of erythropoiesis-stimulating agents (ESAs) in cancer and related neoplastic conditions. Based on Amgen's preliminary review, it appears that CMS has adopted a policy that will limit the availability of these vital medicines to Medicare beneficiaries with cancer. While the decision makes several positive changes from the earlier proposed NCD, ESA treatment is not covered if the patient's hemoglobin (Hb) level is greater than 10 g/dL.

"The coverage restrictions placed on the FDA-approved indication have no scientific basis and are incompatible with good clinical practice," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Global Research and Development at Amgen. "We are concerned that inappropriately limiting coverage for ESAs at hemoglobin levels less than 10 g/dL will both increase blood transfusions and severely compromise the high quality of cancer care delivered by American physicians. In our view, restricting coverage in this way is unreasonable, impractical and unworkable. Moreover, through this coverage decision, the CMS has undermined the ability of physicians to decide how best to administer ESA therapy to their patients through carefully defined dosing guidance articulated by the FDA."

Limiting reimbursement to only patients who have a Hb level that is less than 10 g/dL is contrary to the U.S. Food and Drug Administration's (FDA) approved labeling for ESAs, the Oncologic Drugs Advisory Committee's (ODAC) recommendation against changing the upper hemoglobin limit of 12 g/dL in the current FDA label, and clinical practice guidelines from the American Society of Clinical Oncology (ASCO) and the American Society of Hematology (ASH). In addition, this criterion runs counter to the strongly held views of many patient groups, physicians, and other members of the oncology community who argued in response to the draft NCD for a coverage range up to 12 g/dL.

The decision makes several positive changes from the earlier proposed NCD, including:

-- ESA treatment for anemia due to chemotherapy is covered across all tumor types, and will be covered for eight weeks following the final dose of myelosuppressive chemotherapy.

-- Concomitant use with certain biologic therapies, such as Vectibix(TM) (panitumumab) and Avastin(R) (bevacizumab) was not excluded.

-- Coverage of ESAs for myelodysplastic syndromes (MDS) based on decisions by local carriers was retained.

-- The Hb level at which covered ESA therapy could be initiated was increased from 9 g/dL to 10 g/dL.

-- Coverage of ESAs was extended without requiring patients to enroll in clinical research programs or clinical trials, which CMS had raised as a possibility in its proposed NCD.

CMS also included some restrictions from the proposed NCD that many in the oncology community supported, including the following: any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis; the anemia associated with the treatment of acute and chronic myelogenous leukemias (AML and CML), or erythroid cancers; any anemia associated only with radiotherapy; prophylactic use to prevent chemotherapy-induced anemia; prophylactic use to reduce tumor hypoxia; patients with erythropoietin-type resistance due to neutralizing antibodies; and anemia due to cancer treatment if patients have uncontrolled hypertension. In our communications with CMS, Amgen recommended that CMS finalize these restrictions. In the final NCD, CMS did so.

Details of the final NCD, which is effective as of July 30, 2007, are available at https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=203.

CMS issued its proposed NCD on May 14, 2007 and accepted public comments on the proposal until June 13, 2007. On June 1, 2007, Amgen submitted a detailed response to the proposed NCD and offered specific scientific and clinical recommendations for the agency's consideration in preparing a finalized NCD on ESAs for non-renal indications. Amgen's full response is available at www.amgen.com.

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 May 29, 2007 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 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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