Amgen to Provide New Evidence as Part of a Formal Reconsideration of CMS' National Coverage Determination on ESAs

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Revised Class Labeling and Data on Increased Transfusions are Part of the Growing New Evidence to Revise the Policy

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Nov. 8, 2007--Amgen (NASDAQ:AMGN) today announced its intention to submit new evidence to the Centers for Medicare and Medicaid Services (CMS) to support a reconsideration of the agency's National Coverage Determination (NCD) on Erythropoiesis Stimulating Agents (ESAs). The Company plans to file its request shortly.

The oncology community, Amgen, and CMS have worked collaboratively to arrive at consensus-based, patient-centric provisions for most aspects of the NCD. However, the Company shares the serious concerns voiced by physicians and their patients that the hemoglobin ceiling of 10 grams per deciliter (g/dL) should be reconsidered. This restriction prevents oncologists from effectively managing chemotherapy-induced anemia with ESAs, subjects Medicare beneficiaries to an untested treatment regimen that is not based on scientific evidence, and requires Medicare patients to undergo otherwise avoidable red blood cell transfusions.

Upon reconsideration, a revised policy should be implemented, allowing physicians to follow evidence-based clinical practice guidelines developed by experts in oncology and hematology and to exercise discretion to use their best clinical judgment to treat individual patients based on their unique medical needs. After consultation with leading scientific and clinical experts, practicing physicians, and with patients, Amgen intends to base its formal request for reconsideration on the growing body of new evidence that supports the need for a change in the hemoglobin ceiling of 10 g/dL, to enable oncologists to manage patients within the range of 10-12 g/dL recognized to represent the safe and effective use of ESAs. The body of new evidence includes the following:

- On Oct. 22, the American Society of Hematology and the American Society of Clinical Oncology revised their evidenced-based clinical practice guidelines to reflect a target range of 10 g/dL to 12 g/dL, following a rigorous and evidence-based review by cancer experts. Again, this treatment range recommended by the leading clinical authorities in the United States stands in contrast to the NCD provision that denies coverage for ESAs above a hemoglobin level of 10 g/dL.

- On Nov. 8, Amgen announced that it has updated the Aranesp(R) (darbepoetin alfa) and EPOGEN(R)/PROCRIT (Epoetin alfa) package inserts in collaboration with the U.S. Food and Drug Administration (FDA). The new package inserts strengthen the warnings about ESA risks and confirms that physicians should use the lowest dose that avoids transfusions. Importantly, the label provides for a physician's discretion to use ESAs to achieve a hemoglobin level not to exceed the upper safety limit of 12 g/dL in patients. This approach stands in contrast to the NCD provision that denies coverage for ESAs above a hemoglobin level of 10 g/dL.

- On Oct. 29, the European Agency for the Evaluation of Medicinal Products (EMEA) issued a press release about upcoming changes to product information for ESAs stipulating a uniform target hemoglobin range for all ESAs of 10 g/dL to 12 g/dL with a warning not to exceed a concentration of 12 g/dL. The treatment range approved by the EMEA also stands in contrast to the NCD provision that denies coverage for ESAs above a hemoglobin level of 10 g/dL.

- Major U.S. health plans announced that they will continue to base their coverage policies on evidence-based clinical practice guidelines and not adopt the NCD. In this regard, the NCD has created an unprecedented two-tiered healthcare system based solely on insurance status: one for patients covered by Medicare and another for those with private healthcare coverage.

-On Nov. 4, the German Hodgkins Study Group (GHSG) presented interim results from an independent investigator-sponsored study. This is one of the largest randomized trials of ESAs in patients with Hodgkin's Lymphoma. The interim data show no significant difference between Epoetin alfa and placebo on overall survival and serious adverse events. Additionally, there were significantly less RBC transfusions in the Epoetin alfa group compared to placebo.

- On Sept. 26, Amgen submitted new data presented at the European Cancer Conference (ECCO). This analysis suggests that achieving target hemoglobin levels through the use of red blood cell transfusions may be associated with less favorable survival outcomes.

- In its reconsideration request Amgen will provide new evidence describing a trend towards increased transfusion utilization among patients over age 65 who have received chemotherapy in several institutions.

- On Oct. 22, Amgen announced that it has developed a comprehensive pharmacovigilence program designed to address outstanding questions about ESA safety in both investigational and labeled settings.

- Amgen has implemented a robust risk management plan to ensure that providers and patients are made aware of important new data related to ESA safety including communication with physicians via Dear Health Care Provider letters, and direct communications to patients via upcoming Medication Guides.

"Amgen is committed to the highest standard of patient safety and encourages CMS to revise its NCD based on the growing body of compelling new evidence," said Roger M. Perlmutter, M.D., Ph.D., Amgen's executive vice president of Research and Development. Perlmutter added, "Important revisions in the NCD are needed, so physicians can deliver cancer care using their best clinical judgment with the goal of providing the best possible care to Medicare beneficiaries suffering from cancer."

In the Company's reconsideration request, Amgen intends to request a narrow revision in the policy designed to allow physicians to treat patients between a hemoglobin range of 10 to 12 g/dL when such treatments have been certified as medically appropriate and in a manner consistent with the new FDA-approved product labeling and the recently revised evidence-based clinical practice guidelines.

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 involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended Dec. 31, 2006, and in our 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) and 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. 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 product 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; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers.

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