Amgen Receives Executive Summary from Independent Cochrane Collaboration Review of ESAs in Oncology

September 30, 2008

THOUSAND OAKS, Calif., Sep 30, 2008 (BUSINESS WIRE) -- Amgen Inc., (NASDAQ: AMGN) announced it has received a summary of preliminary results from the Cochrane Collaboration's independent meta-analysis of patient-level data from previously conducted, randomized, controlled, clinical studies evaluating erythropoiesis-stimulating agents (ESAs) in cancer patients. Amgen has submitted the executive summary to regulatory authorities, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMEA).

"The Cochrane Collaboration's analysis corroborates important information already reflected in the recently revised ESA labeling, which physicians and patients should consider when making individual treatment decisions," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "Amgen is working diligently with the FDA to initiate prospective studies that address ongoing questions regarding survival when ESAs are used according to the current prescribing information."

The preliminary summary includes four components: on-study deaths and overall survival in cancer patients regardless of their specific cancer treatment (chemotherapy, radiochemotherapy, radiotherapy, anemia of cancer with no treatment, other), and on-study deaths and overall survival in patients receiving chemotherapy (the only population for which ESA treatment is indicated in current FDA-approved labeling).

The analyses on all cancer patients were based on 53 previously conducted studies involving 13,933 patients. None of these studies utilized ESAs according to current label guidance. The overall survival results corroborate an earlier review by the Cochrane Collaboration, published in 2006, which is included in the WARNINGS section of the current U.S. prescribing information (HR: 1.08 [95 percent CI 0.99-1.18]). ESAs increased on-study deaths (HR: 1.17 [95 percent CI 1.06 -- 1.30]) and decreased overall survival (HR: 1.06 [95 percent CI 1.00 -- 1.12]) compared to controls.

The analyses on patients undergoing chemotherapy, the cancer indication for which ESAs are approved, were based on 38 studies with 10,441 patients. None of these studies utilized ESAs according to current label guidance. ESAs increased on-study deaths (HR: 1.10 [95 percent CI 0.98 -- 1.24]) and decreased overall survival (HR: 1.04 [95 percent CI 0.97 -- 1.11]) compared to controls. While neither of these results is statistically significant, they do not exclude the potential for adverse outcomes when ESAs are used according to the current label.

Amgen believes these results emphasize the importance of adherence to the current ESA labeling, which details these and other risks. To decrease these risks, physicians should use the lowest ESA dose needed to avoid red blood cell transfusion, and only for treatment of anemia due to concomitant myelosuppressive chemotherapy. ESAs are not indicated for cancer patients receiving myelosuppressive therapy when the anticipated outcome of such therapy is cure.

Amgen is working with the FDA to finalize the Risk Evaluation and Management Strategy (REMS) for ESAs, which will ensure that these and other risks are communicated to physicians and patients. In the meantime, physicians and patients should review the patient Medication Guide and prescribing information in order to make informed treatment decisions based on each patient's unique clinical profile.

To enable a comprehensive analysis of existing data, Amgen, Johnson & Johnson Pharmaceutical Research & Development, Roche and independent investigators submitted patient-level data from randomized, controlled clinical studies of ESAs involving approximately 14,000 patients to the Cochrane Collaboration. Complete results of this independent review of ESA treatment outcomes are expected to be presented at a scientific conference by the Cochrane Collaboration later this year.

About The Cochrane Collaboration

The Cochrane Collaboration is an international not-for-profit and independent organization, dedicated to making up-to-date, accurate information about the effects of healthcare readily available worldwide. It produces and disseminates systematic reviews of healthcare interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions.

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 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 Sept. 30, 2008 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 theinvestigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for theseuses. Only the FDA can determine whether the products are safe and effective for these uses. Healthcareprofessionals shouldrefer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

SOURCE: Amgen Inc.

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