New Biomarker Data Links KRAS Gene to Vectibix(TM) Clinical Response

September 25, 2007

Biomarker Analysis from Randomized, Controlled Trial Represents an Advance in the Science of Anti-EGFR Therapy in Metastatic Colorectal Cancer

BARCELONA, Spain--(BUSINESS WIRE)--Sept. 25, 2007--Amgen (NASDAQ: AMGN) today announced the results of a biomarker analysis that supports KRAS as a predictive clinical biomarker that could be used to select patients who are more likely to respond to treatment with Vectibix(TM) (panitumumab) monotherapy.

These data were generated from an analysis of the Phase 3, randomized, controlled clinical trial that investigated the treatment effect of Vectibix in patients with metastatic colorectal cancer (mCRC). Previously reported results from this study demonstrated that Vectibix monotherapy improved progression-free survival ((PFS), HR 0.54; p less than 0.001)) and response rate (10 percent versus 0 percent) in heavily pre-treated patients with mCRC after failure of standard chemotherapy. The new biomarker analysis met its primary and secondary endpoints by demonstrating that the effect of Vectibix on PFS was confined exclusively to the approximately 60 percent of patients whose tumors harbor normal, non-mutated (wild-type) KRAS. No effect of Vectibix therapy was observed in patients who had tumors with mutations in KRAS regardless of the endpoint studied. These data have been shared with U.S. and global regulatory agencies and have been submitted for peer-reviewed publication.

Additionally, pooled data from three Phase 2 trials and a Phase 3 extension study provide supportive evidence regarding the predictive value of KRAS in Vectibix monotherapy. Results were presented during the Presidential Session at the 14th European Cancer Conference (ECCO) in Barcelona, Spain.

Twenty years of study indicate that KRAS plays an important role in cell growth regulation and oncogenesis. In mCRC, the epidermal growth factor receptor (EGFR) transmits signals through a set of intracellular proteins. Upon reaching the nucleus, these signals instruct the cancer cell to reproduce and metastasize, leading to cancer progression. Anti-EGFR therapies work by blocking the activation of EGFR, thereby inhibiting downstream events that lead to malignant signaling. However, it is hypothesized that in patients with tumors harboring a mutated KRAS gene, the KRAS protein is always turned "on," regardless of whether the EGFR has been activated or therapeutically inhibited.

Thus, in patients with mutant KRAS, signaling continues despite anti-EGFR therapy. Activated KRAS is detected in approximately 40 percent of metastatic colorectal cancer, depending on the testing method used. Multiple studies support anti-EGFR therapy being significantly more effective in patients with non-mutated KRAS.

"Preclinical research has long implicated the RAS oncogene in cancer biology, but now this research may be translated into patient management," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "In the future, physicians may select treatment options specifically for patients whose tumors harbor the non-mutated KRAS gene."

In a second analysis, patient samples from four mCRC monotherapy studies of safety and efficacy with Vectibix were used to generate the hypothesis that tumors with mutated KRAS are associated with drug resistance. Of the 62 patient samples evaluated in the analysis, 21 had the activated KRAS and none responded to therapy. The analysis also found that there was a statistically significant association between KRAS mutation status and response to Vectibix (p=0.013).

"Being able to select which patients may benefit from treatment would reduce the individual patient and societal burdens often associated with cancer therapy," said Tim Turnham, Ph.D., chief executive officer, Colon Cancer Alliance. "The robustness and outcome of this biomarker analysis is an important step forward in advancing the field of personalized cancer care."

Last week the European Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending a conditional marketing authorization for Vectibix(TM) (panitumumab) in the European Union (EU) for patients with refractory metastatic colorectal cancer with non-mutated (wild-type) KRAS genes.

About Vectibix

Vectibix is indicated in the U.S. for the treatment of patients with epidermal growth factor receptor- (EGFR) expressing mCRC after disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan- containing chemotherapy regimens. The effectiveness of Vectibix for the treatment of EGFR-expressing, metastatic colorectal carcinoma is based on progression-free survival. Currently no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

Important Product Safety Information

Dermatologic toxicities, related to Vectibix blockade of EGF binding and subsequent inhibition of EGF receptor-mediated signaling pathways, included but were not limited to dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. Dermatologic toxicities were reported in 89 percent of patients treated with Vectibix and were severe in 12 percent of patients. Severe dermatologic toxicities were complicated by infection, including sepsis, septic death, and abscesses requiring incisions and drainage. Vectibix may need to be withheld or discontinued for severe dermatologic toxicities.

Severe infusion reactions occurred with Vectibix in approximately 1 percent of patients. Severe infusion reactions were identified as anaphylactic reactions, bronchospasm, fever, chills, and hypotension. Although fatal infusion reactions have not been reported with Vectibix, they have occurred with other monoclonal antibody products. Severe infusion reactions require stopping the infusion and possibly permanently discontinuing Vectibix, depending on the severity and/or persistence of the reaction.

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 Sept. 25, 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 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. 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) or European Medicines Agency (EMEA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA, EMEA or comparable regulatory body 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 or EMEA 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, EMEA or comparable regulatory body can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the applicable FDA- or EMEA-approved labeling for the products, and not the information discussed in this news release.

CONTACT: Amgen
Christine Regan, 805-447-5476 (U.S. media)
Sabeena Ahmad, 41-41-3692-530 (EU media)
Arvind Sood (investors), 805-447-1060

SOURCE: Amgen