Oncology Biomarker KRAS to be Discussed at FDA Panel Meeting

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THOUSAND OAKS, Calif., Dec 16, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- KRAS Biomarker Presents Potential to Personalize Colorectal Cancer Treatment Determining Who Can Benefit from Vectibix(R)

Amgen (Nasdaq: AMGN) today announced they will discuss the clinical utility of the KRAS gene as a predictive biomarker in patients with metastatic colorectal cancer (mCRC) treated with anti-epidermal growth factor receptor (EGFr) antibody Vectibix(R) (panitumumab) with the U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC).

We believe that data shared with the Committee support the suggestion that KRAS is a predictive biomarker for the anti-EGFr class of drugs in the monotherapy setting. In March 2008, the Journal of Clinical Oncology published results from an analysis of the first randomized, controlled clinical trial ("408") which showed that mCRC patients with mutated KRAS tumors do not respond to Vectibix monotherapy. Conversely, patients with wild-type KRAS tumors treated with Vectibix have a better response rate and prolonged progression-free survival (PFS).

"These data are consistent with 30 years of biology which indicate that KRAS is a clinically relevant oncogene," said Sean Harper, M.D., chief medical officer and head of Global Development at Amgen. "We believe the data from our "408" monotherapy trial that will be presented today indicate that the benefit-risk profile of Vectibix is improved by restricting use to those patients with mCRC whose tumors have wild-type KRAS genes."

To further independently evaluate the association of KRAS status seen in the "408" trial, additional retrospective analyses of all other studies of Vectibix monotherapy in mCRC were performed. A pooled analysis, presented at the European Society of Medical Oncology in 2008 from over 700 patients (including subjects randomized to Vectibix in "408") will be presented to the Committee for their consideration.

Data that KRAS is a clinically relevant biomarker for Vectibix is confined to the monotherapy setting; there is not yet sufficient data with Vectibix in combination with chemotherapy to conclude that KRAS is a valid predictive biomarker in that setting. However, pivotal studies "181" and "PRIME ("203") will be the first prospective Phase 3 clinical studies to test the effect of Vectibix in wild-type KRAS tumors in combination with chemotherapy and to determine the clinical utility of KRAS as a predictive biomarker in mCRC. Data from these trials will be available in 2009.

"Based on available data, we believe that focusing Vectibix treatment on patients with wild-type KRAS tumors will avoid unnecessary adverse events in patients who are unlikely to benefit, maximize response rates and PFS in patients with wild-type KRAS genes, and redirect patients with a mutated KRAS gene to alternative therapies," said Sean Harper. "We are thrilled to be taking a step forward in advancing the field of personalized medicine by being one of the first to realize the clinical potential of the KRAS gene in guiding treatment of advanced colorectal cancer patients."

In November, the National Comprehensive Cancer Network (NCCN) announced updates to their Guidelines on Colon and Rectal Cancers that included the recommendation that a determination of the KRAS gene status of either the primary tumor or a site of metastasis should be part of the pre-treatment work-up for patients diagnosed with metastatic colorectal cancer. Further, the guidelines recommended that EGFr inhibitors, including Vectibix, should only be used in patients with tumors characterized by the wild-type KRAS gene.

"Amgen is applying the use of cutting-edge science and technology to attempt to target therapies to patients most likely to receive benefit," said Sean Harper. "We are committed to continue our work with the FDA to leverage our understanding of cancer biology in the Research & Development process, integrating biomarkers into ongoing clinical programs whenever scientifically feasible."

For more information on biomarkers and their potential role in the future of cancer treatment, prevention and detection, please visit http://www.amgen.com/media/virtual_press_kits.html.

About Colorectal Cancer

Colorectal cancer is the third most common cancer diagnosed in men and in women in the United States (U.S.). The American Cancer Society estimates that about 108,070 new cases of colon cancer and 40,740 new cases of rectal cancer will be diagnosed in 2008. Colorectal cancer is the second leading cause of cancer death among men and women in the U.S. and it has been estimated that more than 49,000 people will die from colorectal cancer in 2008. That means that one person in the U.S. dies of colorectal cancer every 9.3 minutes.

About Vectibix

Vectibix is indicated for the treatment of patients with epidermal growth factor receptor- (EGFr) expressing metastatic colorectal cancer 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 Toxicity: Dermatologic toxicities occurred in 89 percent of patients and were severe (NCI-CTC grade 3 and higher) in 12 percent of patients receiving Vectibix monotherapy. Withhold Vectibix for dermatologic toxicities that are grade 3 or higher or are considered intolerable. If toxicity does not improve to a%n grade 2 within 1 month, permanently discontinue Vectibix. The clinical manifestations included, but were not limited to, dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. Subsequent to the development of severe dermatologic toxicities, infectious complications, including sepsis, septic death, and abscesses requiring incisions and drainage were reported.

Infusion Reactions: Severe infusion reactions occurred in approximately 1 percent of patients. Severe infusion reactions included anaphylactic reactions, bronchospasm, and hypotension. Although not reported with Vectibix, fatal infusion reactions have occurred with other monoclonal antibody products. Stop infusion if a severe infusion reaction occurs. Depending on the severity and/or persistence of the reaction, permanently discontinue Vectibix.

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 Dec. 16, 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 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 relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (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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