Vectibix(R) in Combination With Chemotherapy Significantly Improves Progression-Free Survival in Second-Line Metastatic Colorectal Cancer

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THOUSAND OAKS, Calif., Sept. 22 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) today announced detailed results from the Phase 3 '181' trial evaluating Vectibix((R)) (panitumumab) in combination with FOLFIRI (an irinotecan based chemotherapy), as a second-line treatment for metastatic colorectal cancer (mCRC). In this trial, Vectibix significantly improved progression-free survival (PFS) in patients with *KRAS* wild-type mCRC. These results were presented at the 2009 ECCO 15 - ESMO 34 European Multidisciplinary Congress in Berlin, Germany (Abstract Number 14LBA).

The addition of Vectibix to FOLFIRI significantly improved median PFS (co-primary endpoint) by two months (5.9 versus 3.9 months for patients treated with FOLFIRI alone, hazard ratio 0.73, p=0.004) in patients with *KRAS* wild-type mCRC. Although numerically greater (14.5 months versus 12.5 months; hazard ratio 0.85), the improvement in median overall survival (co-primary endpoint) in the Vectibix arm did not achieve statistical significance (p=0.115) in the same patient population.

Further, the addition of Vectibix to FOLFIRI resulted in greater than a three-fold improvement (35 percent versus 10 percent) in response rate in the *KRAS* wild-type patient population as measured by a blinded central review.

"This study showed that Vectibix can be safely administered in combination with FOLFIRI chemotherapy. Vectibix delayed disease progression by more than half compared to FOLFIRI alone in patients with previously treated *KRAS* wild-type colorectal cancer," said Marc Peeters, M.D., Ph.D., coordinator of Digestive Oncology Unit, University Hospital Ghent and the study's principal investigator. "Further, the response rate seen in this trial is among the highest ever reported in the second-line metastatic CRC setting."

In general, adverse events rates were comparable across arms with the exception of known toxicities associated with anti-epidermal growth factor receptor (EGFR) therapy such as rash, diarrhea, and hypomagnesemia. Vectibix-related grade 3/4 infusion reactions were reported in less than one percent of patients.

There were no differences in progression-free survival, overall survival and response rates among patients with mutated *KRAS* who received Vectibix.

Originally designed to compare the treatment effect in the overall population, the study was amended to analyze outcomes with respect to the presence or absence of activating mutations in *KRAS* in the tumor itself. Tumor *KRAS* status was ascertained in 91 percent of the 1,186 patients enrolled in this trial, the highest number ever reported for a second-line trial.

"These high quality prospectively defined analyses prove the clinical utility of *KRAS* as a predictive biomarker in metastatic colorectal cancer patients," added Peeters.

Webcast Information

An analyst/investor event will also be held from the Congress on September 24th, at 6:30 a.m. Eastern Time to discuss data presented at ECCO-ESMO. A webcast of the event can be found on Amgen's Web site at *www.amgen.com*, under Investors. The audio webcast will be archived and available for replay for at least 72 hours.

Study Design

The "181" trial is a global, multicenter, randomized Phase 3 study. Patients enrolled in the study were randomized to receive either 6.0 mg/kg of Vectibix and FOLFIRI every two weeks (Q2W) or FOLFIRI alone Q2W. The independently tested co-primary endpoints were progression-free survival and overall survival. Secondary endpoints included objective response rate, time to progression, duration of response and safety by *KRAS* status.

About KRAS

Results from studies performed over the last twenty-five years indicate that *KRAS* plays an important role in cell growth regulation. In mCRC, 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 antibody therapies work by blocking the activation of EGFR, thereby inhibiting downstream events that lead to malignant signaling. However, it is hypothesized that in patients whose tumors harbor a mutated *KRAS* gene, the *KRAS* protein is always turned "on," regardless of whether the EGFR has been activated or therapeutically inhibited. *KRAS* mutations occur in approximately 40 - 50 percent of mCRC.

About Colorectal Cancer

Colorectal cancer is the fourth most common cancer in men and the third most common cancer in women worldwide. In 2007, approximately 1.2 million cases of colorectal cancer were expected to occur globally. With more than 630,000 deaths worldwide per year, it is the second leading cause of cancer-related death in the Western world. The highest incidence rates are found in Japan, North America, parts of Europe, New Zealand, and Australia, and rates are low in Africa and South-East Asia.( ) Rates are substantially higher in men than in women.

About Vectibix

Vectibix is the first fully human anti-EGFR antibody approved by the U.S. Food and Drug Administration (FDA) for the treatment of mCRC. Vectibix was approved in the United States in September 2006 as a monotherapy for the treatment of patients with EGFR expressing mCRC after disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

The effectiveness of Vectibix as a single agent 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. Vectibix

has not shown a treatment benefit for patients whose tumors had *KRAS* mutations in codon 12 or 13.

In December 2007, the EMEA granted a conditional marketing authorization for Vectibix as monotherapy for the treatment of patients with EGFR-expressing mCRC with wild-type *KRAS* genes after failure of standard chemotherapy regimens. Vectibix has been launched in over 20 countries, Switzerland, Australia and Canada. Applications in the rest of the world, including Japan, are pending.

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 less than or equal to 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 Sept. 22, 2009 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 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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