Amgen Presents Complete Results From Two Pivotal Phase 3 Studies of Vectibix(R) at Gastrointestinal Cancers Symposium

January 21, 2010
THOUSAND OAKS, Calif., Jan 21, 2010 /PRNewswire via COMTEX/ -- Amgen (Nasdaq: AMGN) today announced that detailed results from two pivotal Phase 3 studies evaluating Vectibix(R) (panitumumab) in combination with chemotherapy for the first and second-line treatment of metastatic colorectal cancer (mCRC) (the PRIME '203' and '181' trials, respectively) will be presented at the 2010 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium in Orlando, Florida from Jan. 22-24, 2010.

"The results from the 203 and 181 trials evaluating Vectibix administered in combination with chemotherapy in first and second-line treatment provide important information for patients with metastatic colorectal cancer and the physicians who care for them," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "Our data reinforce the importance of the *KRAS* mutation as a predictive biomarker for responsiveness to Vectibix therapy. We believe that *KRAS* testing should be conducted in all patients with colorectal cancer soon after diagnosis, to allow physicians to choose the most appropriate treatment strategies for their patients."

Full data from these two pivotal Phase 3 studies will be presented on Sunday, January 24, at 10:30 a.m. (EST). Identified below are selected abstracts of interest. Updated data will be presented at the meeting.

SELECTED ABSTRACTS OF INTEREST

-- Randomized phase 3 study of panitumumab (pmab) with FOLFIRI vs FOLFIRI alone as 2nd-line treatment (tx) in patients (pts) with metastatic colorectal cancer (mCRC): Patient reported outcomes (PRO)
Lead Author: Peeters M
Abstract No. 282 (Sunday, Jan. 24, 2010, 10:30 a.m.-12:00 p.m.)

-- Randomized phase 3 study of panitumumab (pmab) with FOLFOX4 compared to FOLFOX4 alone as first-line treatment (tx) for metastatic colorectal cancer (mCRC): PRIME trial
Lead Author: Siena S
Abstract No. 283 (Sunday, Jan. 24, 2010, 10:30 a.m.-12:00 p.m.)

-- Primary analysis of a phase II study (20060314) combining first line panitumumab (pmab) with FOLFIRI in the treatment of patients (pts) with metastatic colorectal cancer (mCRC)
Lead Author: Koehne C-H
Abstract No. 414 (Sunday, Jan. 24, 2010, 7:00-8:00 a.m., 12:00-1:00 p.m.)

-- Epidermal-growth factor receptor (EGFR) inhibitor-related skin toxicity: review of primary analysis data from a phase II study (20060314) of panitumumab (pmab) with FOLFIRI in the first line treatment of metastatic colorectal cancer (mCRC)
Lead Author: Karthaus M
Abstract No. 429 (Sunday, Jan. 24, 2010, 7:00-8:00 a.m., 12:00-1:00 p.m.)

About Vectibix

Vectibix is the first fully human anti-EGFR antibody approved by the United States (U.S.) Food and Drug Administration (FDA) for the treatment of mCRC. Vectibix was approved in the U. S. in September 2006 as monotherapy for the treatment of patients with EGFRexpressing metastatic colorectal carcinoma 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. Retrospective subset analyses of metastatic colorectal cancer trials have not shown a treatment benefit for Vectibix in patients whose tumors had *KRAS* mutations in codon 12 or 13. Use of Vectibix is not recommended for the treatment of colorectal cancer with these mutations.

In December 2007, the European Medicines Agency (EMA) granted a conditional marketing authorization for Vectibix as monotherapy for the treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) *KRAS* after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. Vectibix has been launched in over 20 EU countries, Russia, Switzerland, Australia and Canada. Applications in the rest of the world 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 http://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 Jan. 21, 2010 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.

CONTACT: Amgen, Thousand Oaks
Ashleigh Koss: +1 (805) 313-6151 (media)
Arvind Sood: +1 (805) 447-1060 (investors)

(Logo: http://www.newscom.com/cgi-bin/prnh/20081015/AMGENLOGO)

SOURCE Amgen