Randomized Phase 3 Trial Shows Panitumumab Significantly Improved Progression-Free Survival and Disease Control in Metastatic Colorectal Cancer Patients

April 3, 2006

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--April 3, 2006--Amgen (Nasdaq:AMGN), the world's largest biotechnology company, today announced pivotal Phase 3 results demonstrating that panitumumab significantly improved progression-free survival and disease control (response rate and stable disease) compared to best supportive care (BSC) in metastatic colorectal cancer patients who had failed standard chemotherapy. The results were presented in a Clinical Plenary Session at the 97th Annual Meeting of the American Association for Cancer Research (Abstract #CP-1).

"Panitumumab reduced the rate of disease progression by approximately half compared to best supportive care alone in these heavily pre-treated patients," said Marc Peeters, M.D., Ph.D., coordinator of Digestive Oncology Unit, University Hospital Ghent, and one of the study's lead investigators. "Furthermore, the difference in objective response rates and the proportion of patients with disease stabilization between panitumumab and best supportive care alone demonstrated the significant activity of this agent."

In this multi-national, open-label Phase 3 study, 463 patients with metastatic colorectal cancer who had failed standard chemotherapy, including oxaliplatin and irinotecan, were randomized to receive 6 mg/kg panitumumab plus BSC (n=231) every two weeks or BSC alone (n=232). An independent, central radiology review board assessed disease progression and tumor shrinkage.

Patients who received panitumumab every two weeks showed a 46 percent decrease in tumor progression rate versus those who received best supportive care alone (p less than 0.000 000 001). A significantly higher proportion of patients were alive and free of disease progression on panitumumab at all of the scheduled time points through week 32. For example, after six months (week 24) approximately four times as many panitumumab-treated patients were alive and progression-free (18 percent versus five percent with BSC alone). Twice as many panitumumab-treated patients were alive and progression-free at week 32 (10 percent versus four percent with BSC alone).

Study investigators also reported that panitumumab significantly improved disease control versus BSC alone (36 percent versus 10 percent, respectively), as measured by response rate and stable disease. The objective, independently evaluated response rate was eight percent with panitumumab versus zero with BSC alone, and the median duration of response was 17 weeks. The stable disease rate was 28 percent with panitumumab versus 10 percent with BSC alone.

Approximately 75 percent of the best supportive care patients entered a cross-over arm to receive panitumumab after their disease had progressed (n=174). Panitumumab treatment also showed a clinical benefit in the patients crossing over from the BSC arm, despite their disease progression. In these patients, panitumumab treatment resulted in a nine percent partial response and 32 percent stable disease, as well as one complete response.

An interim analysis of overall survival between the two groups was similar. The rate (75 percent) and timing (median 7.0 weeks) of crossover from the BSC alone arm to receiving panitumumab, and the anti-tumor activity observed after crossover, likely confounded the ability to demonstrate a treatment effect on overall survival (Hazard ratio = 0.93).

Panitumumab improved progression-free survival and response rate regardless of the measured level or intensity of EGFr staining. Improvements in progression-free survival and disease control also occurred regardless of age, sex, primary tumor location (colon versus rectum), or performance status.

Per protocol, administration of panitumumab did not require pre-medication or a loading dose and the incidence of infusion reactions (of any severity) was low (one percent). There were no grade 3 or 4 infusion reactions. More patients in the panitumumab arm reported skin toxicities, fatigue, abdominal pain, nausea and diarrhea. Hypomagnesemia was observed in 38 percent of panitumumab-treated patients (three percent Grade 3/4). No de novo human anti-human antibody (HAHA) or anti-panitumumab antibody formation was observed. In patients with anti-panitumumab antibodies, there was no impact on efficacy, safety and pharmacokinetics.

Patients and physicians can access www.amgentrials.com for more information about ongoing panitumumab clinical trials.

Webcast Information

Amgen will host a webcast with the investment community today at 12:30 P.M. EDT to discuss the Phase 3 data. Open to members of the news media, investors and the general public, the webcast can be found on Amgen's Web site, www.amgen.com, under Investors. It will be archived and available for replay at least 72 hours after the event.

About Panitumumab

Panitumumab is an investigational fully human monoclonal antibody that targets the epidermal growth factor receptor (EGFr), a protein that plays an important role in cancer cell signaling. Panitumumab, an IgG2 monoclonal antibody, binds with high affinity to the EGFr. Panitumumab was generated with XenoMouse(R) technology, which creates a fully human monoclonal antibody that contains no murine (mouse) protein. The body's immune system can recognize the mouse protein found in chimeric and humanized antibodies as foreign and launch an immune response in the form of infusion reactions, allergic reactions or anaphylaxis. The goal of developing fully human monoclonal antibodies is to offer effective, high affinity therapies that minimize the potential for this type of immune response.

Panitumumab received Fast Track designation from the U.S. Food and Drug Administration (FDA) in July 2005 for patients with metastatic colorectal cancer who have failed standard chemotherapy treatment. It is being evaluated in clinical trials as both a monotherapy and in combination with other agents for the treatment of various types of cancer, including colorectal, lung and head and neck.

About the Epidermal Growth Factor Receptor (EGFr)

Although EGFr normally helps regulate the growth of many different cells in the body, EGFr also can stimulate cancer cells to grow. In fact, many cancer cells actually require signals mediated by EGFr for their survival. Residing on the surface of these tumor cells, EGFr is activated when naturally occurring proteins in the body, such as epidermal growth factor (EGF) or transforming growth factor alpha (TGF-alpha), bind to it. This binding changes the shape of EGFr, which, in turn, triggers internal cellular signals that stimulate tumor cell growth. Panitumumab binds to EGFr, preventing the natural ligands such as EGF and TGF-alpha from binding to the receptor and interfering with the signals that would otherwise stimulate growth of the cancer cell and allow it to survive.

About Colorectal Cancer

Colorectal cancer is the third most common cancer diagnosed in men and in women in the United States. The American Cancer Society estimates that about 106,680 new cases of colon cancer and 41,930 new cases of rectal cancer will be diagnosed in 2006.

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 broad and deep 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 Statement

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended December 31, 2005, and in Amgen's periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify side effects or manufacturing problems with Amgen's products after they are on the market.

In addition, sales of Amgen's products are affected by the availability of reimbursement and the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. In addition, Amgen competes with other companies with respect to some of Amgen's marketed products as well as for the discovery and development of new products. Amgen believes that some of the newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen 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 Amgen routinely obtains patents for Amgen's products and technology, the protection offered by Amgen's patents and patent applications may be challenged, invalidated or circumvented by Amgen's competitors and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for Amgen's products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of Amgen's existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of Amgen's products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's 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 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.

EDITOR'S NOTE: An electronic version of this news release may be accessed via our Web site at www.amgen.com. Journalists and media representatives may sign up to receive all news releases electronically at time of announcement by filling out a short form in the Media section of the Web site.

CONTACT: Amgen, Thousand Oaks
Trish Hawkins/Kristen Davis, 805-447-4587 (media)
Arvind Sood, 805-447-1060 (investors)

SOURCE: Amgen