Final Vectibix(TM) Positive Pivotal Phase 3 Trial Results In Metastatic Colorectal Cancer Patients Published

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THOUSAND OAKS, Calif.--(BUSINESS WIRE)--April 30, 2007--Amgen (NASDAQ:AMGN), today announced final results from a pivotal Phase 3 trial which showed that Vectibix(TM) (panitumumab), a fully human monoclonal antibody directed against the epidermal growth factor receptor (EGFr), prolonged progression-free survival (PFS) compared to best supportive care (BSC) in metastatic colorectal cancer patients who had failed fluoropyrimidine, irinotecan, and oxaliplatin containing chemotherapy regimens. The results were published in the May issue of the Journal of Clinical Oncology.

"Medical advances in the treatment of first- and second-line colorectal cancer have improved survival rates; however, most patients develop resistance to these therapies, creating the need for an active agent to treat patients with advanced disease," said Professor Eric Van Cutsem, M.D., Ph.D., Digestive Oncology Unit, University Hospital Gasthuisberg, Leuven, Belgium, lead author of the manuscript. "Final results from the first large randomized trial of its kind show that Vectibix provides a benefit in this heavily pre-treated patient population."

The September 2006 Food and Drug Administration (FDA) approval of Vectibix was based on the results from this multi-national, open-label, randomized study of 463 patients. Patients were randomized to receive 6 mg/kg Vectibix plus BSC (n=231) every two weeks or BSC alone (n=232) until disease progression or unacceptable toxicity. An independent, central radiology review board assessed disease progression and tumor shrinkage. BSC patients determined to have disease progression were eligible to cross-over to a separate study and receive Vectibix.

The primary endpoint of this study was an improvement in progression-free survival. Co-secondary study endpoints were best objective response by blinded central review and overall survival time. The effectiveness of Vectibix for the treatment of EGFr-expressing, metastatic colorectal cancer is based on progression-free survival. Currently no data are available that demonstrate increased survival with Vectibix.

As seen in previous analyses of these data, the Vectibix group showed a statistically significant improvement in progression-free survival versus those who received BSC alone yielding a 46 percent decrease in the relative progression rate. The mean progression-free survival was 96 versus 60 days.

A blinded central review showed that 10 percent of patients in the Vectibix group had an objective response, while no patients in the BSC group demonstrated an objective response. Median time to response was 7.9 weeks and median duration of response was 17 weeks.

In the BSC group 174 (75 percent) patients received Vectibix under the crossover protocol. In those patients that crossed over, the objective response rate was 10 percent. The median time to crossover was 7.0 (6.6, 7.3) weeks. The median follow-up after crossover was 27 (4-69) weeks.

In the primary analysis of overall survival, there was no significant difference between the groups. The median follow-up time was 72 weeks for all patients.

A broadly-based clinical development program designed to examine the utility of Vectibix in the first- and second-line treatment of metastatic colorectal cancer, as well as head and neck cancer is ongoing.

Important Product Safety Information

As described below, the Vectibix Prescribing Information includes warning language:

Dermatologic toxicities, related to Vectibix blockade of EGF binding and subsequent inhibition of EGFr-mediated signaling pathways, were reported in 89 percent of patients and were severe (NCI-CTC grade 3 and higher) in 12 percent of patients receiving Vectibix monotherapy. The clinical manifestations included, but were not limited to, dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. 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 by reports of anaphylactic reaction, bronchospasm, fever, chills, and hypotension. Although fatal infusion reactions have not been reported with Vectibix, fatalities 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.

Other important safety information includes:

The most common adverse reactions observed with Vectibix were skin rash with variable presentations, hypomagnesemia, paronychia, fatigue, abdominal pain, nausea and diarrhea. Hypomagnesemia occurred 6 weeks or longer after the initiation of Vectibix. In some patients, hypomagnesemia was associated with hypocalcemia.

Vectibix is indicated for the treatment of EGFr-expressing, metastatic colorectal cancer with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

The effectiveness of Vectibix for the treatment of EGFr-expressing, metastatic colorectal cancer is based on progression-free survival. Currently no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

AmgenTM Oncology Assistance

Amgen has expanded its patient assistance programs into a comprehensive, multifaceted program with a single gateway - AmgenTM Oncology Assistance. Through this program, patients who are uninsured, underinsured, or unable to afford their insurance co-payments can receive financial support for Amgen's cancer medicines, including Vectibix. The Amgen Oncology Assistance program will be available for U.S. cancer patients and will

launch in October. For more information, please visit www.amgen.com.

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 estimated that about 112,340 new cases of colon cancer and 41,420 new cases of rectal cancer will be diagnosed in 2007. Colorectal cancer is the second leading cause of cancer death among men and women in the United States and Canada (after lung cancer). It has been estimated that 52,180 people will die from colorectal cancer in 2007. That means that one person in the United States dies of colorectal cancer every 9.3 minutes.

About Vectibix

Although EGF receptors normally help regulate the growth of many different cells in the body, these receptors also can stimulate cancer cells to grow. In fact, some cancer cells actually require signals mediated by EGF receptors for their survival. Residing on the surfaces of these tumor cells, EGF receptors are activated when naturally occurring proteins in the body, such as epidermal growth factor (EGF) or transforming growth factor alpha (TGF-alpha), bind to them. This binding changes the shape of the EGF receptors, which, in turn, triggers internal cellular signals that stimulate tumor cell growth. Vectibix binds to EGF receptors, preventing the natural ligands such as EGF and TGF-alpha from binding to the receptors and interfering with the signals that might otherwise stimulate growth and survival of the cancer cell.

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, 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 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. 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 or others could identify side effects or manufacturing problems with Amgen's products after they are on the market. 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.

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.

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