FDA Approves Vectibix(TM) to Treat Patients with Metastatic Colorectal Cancer

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Business Editors

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Sept. 27, 2006--Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved Vectibix(TM) (panitumumab) following priority review. Vectibix is the first entirely human monoclonal antibody 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 FDA approval of Vectibix was based on a progression-free survival endpoint. Vectibix is the first anti-EGFr antibody shown to significantly improve progression-free survival in patients with metastatic colorectal cancer. Currently no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Vectibix. Vectibix can be conveniently administered intravenously once every two weeks.

Vectibix is expected to be commercially available in early-to-mid October and will be priced at approximately 20 percent less than the other anti-EGFr antibody currently on the market.

"Vectibix is the first entirely human antibody for the treatment of colorectal cancer to be approved by the FDA. It provides another option for patients with metastatic colorectal cancer that have progressed on all available chemotherapy regimens," said J. Randolph Hecht, M.D., director of the UCLA Gastrointestinal Oncology Program and clinical professor of Medicine, UCLA David Geffen School of Medicine, Los Angeles. "In a large, randomized clinical trial, Vectibix has been shown to delay progression of disease compared to best supportive care."

Epidermal growth factor receptors are proteins that play an important role in cancer cell signaling. Vectibix is an entirely human IgG2 monoclonal antibody that binds with high affinity to EGF receptors. The goal of developing entirely human monoclonal antibodies is to offer effective targeted therapies with lessened risk of immune response against these agents.

"Our goal is to fulfill the promise of biotechnology to improve the way cancer is treated," said Willard Dere, M.D., chief medical officer and senior vice president of Global Development at Amgen. "The approval of Vectibix allows us to build on our strong foundation in supportive care and move forward with our comprehensive approach to helping patients in their fight against cancer."

"One out of 18 people in this country will develop colorectal cancer in their lifetime and 20 percent of colorectal cancers are found after the disease has spread to distant organs." said Amy Kelly, director and co-founder of the Colon Cancer Alliance. "That means that a person in the U.S. is diagnosed with colorectal cancer every four minutes, heightening the need for new therapeutic options such as Vectibix."

Marketing applications were simultaneously submitted to the European Medicines Agency (EMEA) in April 2006 and Health Canada, Australia and Switzerland in May 2006. Vectibix is being evaluated in ongoing clinical trials as both a monotherapy and in combination with other agents for the treatment of various types of cancer. For more information please visit www.amgentrials.com.

Important Product Safety Information

As described below, the Vectibix Prescribing Information includes warning language as part of evolving FDA labeling for the anti-EGFr class:

Dermatologic toxicities, related to Vectibix blockade of EGF binding and subsequent inhibition of EGF receptor-mediated signaling pathways, included but were not limited to dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. Dermatologic toxicities were reported in 89 percent of patients treated with Vectibix and were severe in 12 percent of patients. 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 as anaphylactic reactions, bronchospasm, fever, chills, and hypotension. Although fatal infusion reactions have not been reported with Vectibix, they 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 to Vectibix were generally mild to moderate and included skin rash with variable presentations, 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.

Amgen(TM) Oncology Assistance

Amgen has expanded its patient assistance programs into a comprehensive, multifaceted program with a single gateway - Amgen(TM) 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 146,940 new cases of colon cancer and 41,930 new cases of rectal cancer will be diagnosed in 2006. 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 56,370 people will die

from colorectal cancer in 2006. 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 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. 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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