Abgenix and Amgen Announce FDA Grants Panitumumab Fast Track Designation for Metastatic Colorectal Cancer

August 1, 2005

THOUSAND OAKS, Calif. & FREMONT, Calif.--(BUSINESS WIRE)--Aug. 1, 2005--Amgen (Nasdaq:AMGN) and Abgenix, Inc. (Nasdaq:ABGX) today announced that the U.S. Food and Drug Administration (FDA) has granted fast track designation for panitumumab, an experimental fully human monoclonal antibody directed against the epidermal growth factor receptor (EGFr), for patients with metastatic colorectal cancer who have failed standard chemotherapy treatment.

"We are advancing the development of panitumumab with the hope of offering patients a new treatment option in their fight against metastatic colorectal cancer," said Willard Dere, M.D., chief medical officer and senior vice president of global development at Amgen.

Under the FDA Modernization Act of 1997, fast track designation allows the FDA to accept, on a rolling basis, portions of a marketing application for review prior to the completion of the final registrational package. Fast track designation may potentially expedite the review of a drug that is intended for the treatment of a serious life-threatening condition and demonstrates the potential to address an unmet medical need for such a condition.

In light of this fast track designation, Amgen and Abgenix are working toward initiating the submission of the Biologics License Application (BLA) for panitumumab in patients who have failed prior standard chemotherapy, including irinotecan and oxaliplatin, by the end of 2005. The completed submission of the BLA could extend into the first quarter of 2006, depending on timing and outcome of clinical data. FDA has previously indicated that data from one pivotal trial, once completed, could be acceptable with additional data from other pending studies to support a submission for marketing approval in the United States.

"Panitumumab is the first fully human monoclonal antibody to inhibit EGFr, and fast track designation represents an important milestone in its development," said Bill Ringo, chief executive officer at Abgenix. "We are one step closer to bringing this promising new treatment to patients with advanced colorectal cancer."

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

About Panitumumab

Co-developed by Amgen and Abgenix, panitumumab is an investigational product in a novel class of targeted cancer treatments called epidermal growth factor receptor (EGFr) inhibitors. Panitumumab (formerly ABX-EGF) is the first fully human monoclonal antibody directed against EGFr and is being evaluated as both a monotherapy and in combination with other agents for the treatment of various types of cancer, including colorectal, lung and kidney. Panitumumab was generated with Abgenix's XenoMouse(R)(1) technology, which creates a fully human monoclonal antibody that contains no murine (mouse) protein. The fully human nature of panitumumab may result in a safety profile with a low incidence of infusion reactions, antigenicity and allergic response. These are attributes currently being investigated in clinical trials. Pivotal clinical studies evaluating panitumumab as a third-line monotherapy in colorectal cancer patients are ongoing with an every-other-week dosing regimen.

About the Epidermal Growth Factor Receptor (EGFr)

Although EGFr normally helps regulate the growth of many different cells in the body, EGFr can also 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, epidermal growth factor (EGF) or transforming growth factor alpha (TGFa), 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 EGF and TGFa 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 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.

About Abgenix

Abgenix is a biopharmaceutical company focused on the discovery, development and manufacturing of human therapeutic antibodies. The company's antibody development platform includes a leading technology and state-of-the-art manufacturing capabilities that enable the rapid generation, selection and production of high affinity, fully human antibody product candidates to a variety of disease targets. Abgenix leverages its leadership position in human antibody technology to build a diversified product portfolio through its own development efforts and the establishment of collaborations with multiple pharmaceutical and biotechnology companies. For more information on Abgenix, visit the company's website at www.abgenix.com.

Amgen 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, 2004, 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 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 side effects or manufacturing problems with our products after they are on the market. In addition, sales of our 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 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 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.

Abgenix Forward-Looking Statement

Statements made in this press release about Abgenix's technologies, product development activities and collaborative arrangements, other than statements of historical fact, are forward-looking statements and are subject to a number of uncertainties that could cause actual results to differ materially from the statements made, including risks associated with the timing and success of clinical trials, the progress of research and product development programs, product manufacturing, regulatory approval processes, competitive products and services and the extent and breadth of Abgenix's patent portfolio. Please see Abgenix's public filings with the Securities and Exchange Commission for information about risks that may affect Abgenix, including its Form 10-K for the year ended December 31, 2004, and periodic reports on Form 10-Q and Form 8-K.

(1) XenoMouse(R) is a registered trademark of Xenotech, a wholly-owned subsidiary of Abgenix, Inc.

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, 805-447-4587 (media)
Arvind Sood, 805-447-1060 (investors)
Or
Abgenix
Greg Mann, 510-284-6566 (media & investors)

SOURCE: Amgen