Panitumumab Significantly Improves Progression-Free Survival in Phase 3 Randomized Metastatic Colorectal Cancer Study

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First EGFr Inhibitor to Demonstrate Improvement in Progression-Free Survival as Monotherapy for Metastatic Colorectal Cancer

THOUSAND OAKS & FREMONT, Calif., Nov 03, 2005 (BUSINESS WIRE) -- Amgen (Nasdaq:AMGN) and Abgenix, Inc. (Nasdaq:ABGX) today announced that a pivotal Phase 3 study of panitumumab met the primary endpoint of improving progression-free survival in patients with metastatic colorectal cancer (mCRC) who had failed standard chemotherapy. In this randomized Phase 3 trial involving 463 patients, those 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 0.000000001).

This result exceeded the pre-specified measure of progression-free survival that the trial was designed to demonstrate (i.e., a 33 percent decrease in tumor progression rate in patients receiving panitumumab versus those receiving best supportive care, as assessed by central radiology review). A secondary endpoint of objective response rate, as assessed by central radiology review, was also met. Analysis of overall patient survival in this study will occur 12 months after the last patient was randomized.

"Amgen is dedicated to developing safe and effective cancer therapies that significantly improve cancer patients' outcomes," said Willard Dere, M.D., chief medical officer and senior vice president of Global Development at Amgen. "We are excited that panitumumab, our most advanced investigational cancer therapeutic, improved progression-free survival and response rate in metastatic colorectal cancer patients who had failed multiple prior chemotherapy regimens. These results will support a BLA submission, which we plan to initiate by the end of the year."

"We are very encouraged by the results of this pivotal study and what panitumumab could mean for patients with advanced colorectal cancer," said Bill Ringo, president and chief executive officer of Abgenix. "The improvement in progression-free survival shown by panitumumab in this study highlights the value of our proprietary technology and product development capabilities. We continue to work closely with our partner, Amgen, towards the regulatory filing and potential commercialization of panitumumab."

Per protocol, administration of panitumumab did not require administration of pre-medication or a loading dose, and the incidence of infusion reactions (of any severity) was low. An initial safety evaluation showed that the adverse events observed were consistent with previous clinical studies of panitumumab. The most common side effect was acneiform rash. Other side effects less commonly observed were fatigue, nausea and mild diarrhea. No human anti-human antibody (HAHA) or anti-panitumumab antibody formation was observed.

Complete analyses of data from this trial will be submitted for presentation at a medical meeting in 2006.

Panitumumab received Fast Track designation from the U.S. Food and Drug Administration (FDA) in July 2005. Amgen and Abgenix are working toward initiating the submission of the Biologics License Application (BLA) to the FDA for panitumumab in patients who have failed prior standard chemotherapy, including oxaliplatin and irinotecan, by the end of 2005. FDA has previously indicated that data from one pivotal trial, once completed, could be acceptable with additional data from other ongoing studies to support a submission for marketing approval in the United States. The completed submission of the BLA is expected in the first quarter of 2006.

Currently, panitumumab is being investigated as a single agent or in combination with other agents across multiple lines of treatment for various cancers. Patients and physicians can access www.amgentrials.com for more information about ongoing panitumumab clinical trials.

About the Phase 3 Study

The international, multi-center, open-label, controlled Phase 3 study was conducted in Europe, Australia and Canada, and enrolled 463 patients with metastatic colorectal cancer who had failed standard chemotherapy, including oxaliplatin and irinotecan. Patients were randomized to receive panitumumab plus best supportive care (n=231) or best supportive care alone (n=232). Those eligible received panitumumab by intravenous infusion at a dose of 6 mg/kg once every two weeks. There was no requirement that patients receive any pre-medication prior to panitumumab administration.

Best supportive care was defined as the best palliative care available, as judged appropriate by the investigator, and could include antibiotics, analgesics, radiation therapy for pain control (limited to bone metastases), corticosteroids, transfusions, psychotherapy, growth factors, palliative surgery, or any other symptomatic therapy as clinically indicated. For the purposes of this study, best supportive care did not include anti-cancer chemotherapy.

Conference Call Information

Amgen and Abgenix will host a conference call with the investment community today at 8:00 a.m. Pacific Time. Participating in the call will be Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen, and Bill Ringo, president and chief executive officer at Abgenix.

Live audio of the conference call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public.

To participate in the conference call, please dial 877-817-2450 or 706-634-7548 fifteen minutes before start time. The pass code for the live call is 2201994. A telephonic replay of the call will be available by dialing 800-642-1687 or 706-645-9291. The replay participant code is 2201994.

The webcast of the conference can be found on Amgen's Web site, www.amgen.com, under Investors, and on Abgenix's Web site, www.abgenix.com. The webcast will be archived and available for replay at least 72 hours after the event.

About Panitumumab

Co-developed by Amgen and Abgenix, panitumumab is the first 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 Abgenix's XenoMouse(R)(1) 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 antibodies as foreign and launches an immune response in the form of infusion reactions, allergic reactions or anaphylaxis. The goal of developing fully human monoclonal antibodies, which by definition contain no mouse protein, is to offer effective, high affinity therapies that minimize the potential for this type of immune response. Panitumumab 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 kidney.

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 104,950 new cases of colon cancer (48,290 men and 56,660 women) and 40,340 new cases of rectal cancer (25,530 men and 16,810 women) will be diagnosed in 2005.

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 fully 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 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.

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, timing and outcomes of 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.

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