Further Phase 2 Data Confirm Panitumumab Single-Agent Antitumor Activity in Patients with Metastatic Colorectal Cancer

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ORLANDO, Fla., May 17, 2005 (BUSINESS WIRE) -- Amgen Inc. (NASDAQ:AMGN), the world's largest biotechnology company, and Abgenix, Inc. (NASDAQ:ABGX), a leading antibody development company, today announced updated results from an ongoing Phase 2 study of panitumumab, a fully human monoclonal antibody directed against the epidermal growth factor receptor (EGFr). The results demonstrate that panitumumab has antitumor activity when administered as a single-agent treatment to patients with metastatic colorectal cancer (mCRC) who have failed standard chemotherapy. An independent central radiology review determined that treatment with panitumumab resulted in a nine percent overall response rate and median time to progression of 11.4 weeks. (Abstract #3520)

The data were presented today at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO). Investigators reported that patients with mCRC tumors expressing the EGFr protein who received panitumumab monotherapy demonstrated a median survival time of 37.6 weeks and a median duration of tumor response of 18.1 weeks. Stabilization of disease was observed in 29 percent of patients (n=43). Median progression-free survival time was 13.6 weeks.

"These data confirm previously reported safety and response findings in patients with metastatic colorectal cancer who have previously failed multiple lines of chemotherapy," said Imtiaz A. Malik, M.D., professor of medicine, Loma Linda University Cancer Institute, Loma Linda, Calif. and one of the study's lead investigators. "Panitumumab's efficacy and safety data from Phase 1 and Phase 2 clinical trials to date suggest that panitumumab may provide an additional avenue for oncologists to manage the disease."

Patients in the study (n=148) were previously treated with 5FU (with or without leucovorin) and either irinotecan or oxaliplatin, or both. Patients received 2.5 mg/kg of panitumumab by weekly one-hour intravenous infusion without premedication. Tumor responses were confirmed no less than four weeks after the initial response was observed.

In this Phase 2 study, the most common side effect was skin toxicity (95 percent, 7 percent grade 3). Other side effects experienced by some patients were fatigue, nausea and mild diarrhea. One infusion reaction (grade 3) was reported per investigator assessment and the patient continued on full-dose panitumumab with pre-medication. There were no instances of anaphylaxis observed. In those patients tested who had a baseline and a post-baseline assessment (n=107), no human antihuman antibodies (HAHAs) formation was observed.

Phase 1 Open-Label Dose Escalation Trial Suggests Panitumumab May Provide for Flexible Dosing Schedules in Cancer Patients (Poster K4, Abstract #3059)

Additional data from a Phase 1 open-label dose escalation trial were presented by Louis M. Weiner, M.D., chairman, department of medical oncology, and vice president, translational research at Fox Chase Cancer Center, Philadelphia, Pa. Exposure and tolerability profiles were similar between weekly, every-other-week and every-three-week dosing schedules.

"We are very encouraged by the safety profile at various doses of this antibody in cancer patients and in different types of cancers. We look forward to the continued evaluation of panitumumab, a promising antibody cancer therapeutic," said Dr. Weiner.

Patients (n=96) were randomized to receive four infusions of panitumumab at different dose levels and schedules ranging from 0.01 to 5.0 mg/kg once per week, 6.0 mg/kg once every two weeks or 9.0 mg/kg once every three weeks administered by intravenous infusion with no premedication required.

For further information concerning ongoing clinical trials involving panitumumab please visit, http://www.amgentrials.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 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 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 and antigenicity. These are attributes currently being investigated in clinical trials. Pivotal clinical studies evaluating panitumumab as a monotherapy in colorectal cancer patients who have failed standard chemotherapy 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 is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

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 the establishment of collaborations with multiple pharmaceutical and biotechnology companies. For more information on Abgenix, visit the company's Web site 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.

SOURCE: Amgen Inc.

Amgen
Trish Hawkins, 805-447-4587 (media)
Arvind Sood, 805-447-1060 (investors)
or
E. Blair Schoeb, 917-432-9275 (media & investors)