



## **Interim Phase 2 Data Suggest Activity of Panitumumab with Chemotherapy in First-Line Treatment of Metastatic Colorectal Cancer**

VIENNA, Austria--(BUSINESS WIRE)--Nov. 1, 2004--Amgen Inc. (Nasdaq:AMGN) and Abgenix (Nasdaq:ABGX) today announced interim data from part one of an ongoing Phase 2 study suggesting panitumumab, the first fully human monoclonal antibody that inhibits the epidermal growth factor receptor (EGFr), has activity as a first-line treatment with chemotherapy in patients with metastatic colorectal cancer (mCRC). Results from part one of this two-part single-arm, open-label phase 2 study were described in a poster presentation at the European Society for Medical Oncology's (ESMO) 29th Congress in Vienna (Abstract # 265).

Patients in part one of the study (n=19) received 2.5 mg/kg weekly of panitumumab administered with standard doses of the Saltz regimen (Irinotecan, 5-Fluorouracil and Leucovorin (IFL)). The primary efficacy endpoint was progression-free survival (PFS) as measured by the Response Evaluation Criteria in Solid Tumors (RECIST). Median progression free survival was 8.2 months (95% confidence interval: 5.4 to 16.5 months). Nine of 19 patients (47 percent) had confirmed objective responses (1 complete response and 8 partial responses) after six weeks of therapy. Six patients (32 percent) had stable disease at week six or later, and one patient had progressive disease at week six as assessed by the investigator.

"These interim data suggest that adding panitumumab to chemotherapy for colorectal cancer produces promising anti-tumor activity. The final results of this ongoing trial should lead to future studies incorporating panitumumab with other active agents in colorectal cancer," said Jordan Berlin, M.D., associate professor of medicine at Vanderbilt-Ingram Cancer Center and the study's lead investigator.

Panitumumab was generally well-tolerated. The most frequent adverse event was skin rash (100 percent; 16 percent grade 3, no grade 4). No patient discontinued therapy due to rash. Diarrhea (47 percent grade 3 or 4) was an expected adverse reaction that has been associated with IFL chemotherapy; in previous studies, panitumumab given by itself has resulted in only generally mild diarrhea (30 percent grade 1 or 2). Other grade 3 or 4 treatment-related adverse events reported in more than 2 patients were abdominal pain (16 percent), dehydration (16 percent), and hypokalemia (low potassium level, 16 percent).

Two minor possibly infusion-related reactions were reported, including one cold sweat (grade 1) and one hypotension (grade 2). These events did not reappear upon additional panitumumab administration. No other infusion-related reactions were reported.

Based on these findings, part 2 of this study (n=24) is ongoing to evaluate safety, pharmacokinetics and efficacy of panitumumab administered with the FOLFIRI regimen (FOLinic acid, Fluorouracil, and IRInotecan), currently the more widely applied of the various irinotecan-based regimens.

### **Additional Pharmacokinetic Data Presented Separately**

Additional pharmacokinetic data from the phase 2 study of panitumumab as a first line treatment in combination with chemotherapy in patients with metastatic colorectal cancer were also presented as a poster (Abstract # 311). In the pharmacokinetic data subset study, exposure to panitumumab and irinotecan was similar to that in previously published reports and abstracts in which either drug was given alone. The study concluded that no apparent pharmacokinetic interactions were observed between panitumumab and irinotecan in metastatic colorectal cancer patients.

### **About Panitumumab**

Co-developed by Amgen and Abgenix, panitumumab is an investigational product in a new class of targeted cancer treatments called epidermal growth factor receptor (EGFr) inhibitors. Panitumumab (formerly ABX-EGF), which was generated with XenoMouse(R) technology, 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. Amgen initiated pivotal trials in the United States and Europe evaluating panitumumab as third-line monotherapy in colorectal cancer patients in January 2004.

### **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](http://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, 2003, 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 US 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 it 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.

#### 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 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.

CONTACT: Abgenix

Ami Knoefler, 510-284-6350 (Media & Investors)

or

Amgen, Thousand Oaks

Trish Hawkins, 805-447-4587 (Media)

Laura Biswas, 805-447-1060 (Investors)

SOURCE: Abgenix and Amgen Inc.