New Interim Phase 2 Data Suggest the Antitumor Activity of Panitumumab in Metastatic Colorectal Cancer

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Panitumumab Antitumor Response Observed in Patients with Either Low or Negative Levels of EGFr Staining; Additional Phase 1 Data Suggest AMG 706 Monotherapy Shows Promise for Advanced Thyroid Cancer

ATLANTA, Jun 03, 2006 (BUSINESS WIRE) -- Amgen (NASDAQ:AMGN), the world's largest biotechnology company, today announced interim results from two Phase 2 studies of panitumumab, an investigational fully human monoclonal antibody that targets the epidermal growth factor receptor (EGFr). Results from both studies suggest that antitumor activity of panitumumab was independent of tumor EGFr expression levels in patients with metastatic colorectal cancer (mCRC) who have failed standard chemotherapy. These data were presented at the 42nd Annual Meeting of the American Society of Clinical Oncology. (Abstract #3547, and Abstract #3548, respectively)

"EGFr staining is an immunohistochemical test to determine the amount of that protein on the surface of cancer cells and has been used to try to figure out who will respond to drugs targeting the receptor," 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, and the lead investigator of one of the studies. "These findings, that responses can be seen to anti-EGFr drugs regardless of tumor EGFr staining levels, show that this test does not identify which patients are most likely to benefit from these targeted treatments. Clearly, we need better ways to decide which patients should get these drugs."

The first study examined mCRC patients with either low or negative (less than one percent positive cells) levels of tumor EGFr staining (the 250 study), while the second evaluated mCRC patients with tumor EGFr levels of at least ten percent (the 167 study). Both ongoing multicenter, open-label, Phase 2 trials are examining antitumor activity of panitumumab in patients with mCRC who have failed standard chemotherapy, including oxaliplatin and irinotecan. Patients in both studies receive panitumumab at 6 mg/kg every two weeks until disease progression or drug intolerability. Tumor assessments are conducted by an independent central radiological review board from week eight until disease progression. The primary study endpoint is objective response at week 16, which are subsequently confirmed. Secondary endpoints include; objective response rate throughout study, duration of response, progression-free survival, overall survival, and safety.

At the time of the interim analysis, the 250 study had enrolled 88 patients, with 23 evaluable for response. Thirteen percent (3/23) who received panitumumab monotherapy had a partial response, including two patients with tumor cells negative for EGFr staining. Stable disease, a cancer that is neither decreasing nor increasing in severity, was observed in 30 percent (7/23) of patients, for a total disease control (PR + SD) of 43 percent. The median progression-free survival time was 13.3 weeks. The study plans to enroll 150 patients.

Study 167 had enrolled 91 patients, and 39 were evaluable for response at the time of interim analysis. At week 16, eight percent of patients (3/39) demonstrated a partial response, 21 percent (8/39) had stable disease and 49 percent (19/39) had disease progression. The median progression-free survival time was 7.6 weeks. The study plans to enroll 300 patients.

The clinical trial protocols did not require pre-medication or a loading dose for administration of panitumumab, and the incidence of infusion reactions was low: three percent (3/88) grade 1 or 2 in the 250 study; one percent (1/88), and one percent (1/91) grade 3 (one of which led to panitumumab discontinuation), in the 250 and 167 studies, respectively. There were no grade 4 or 5 infusion reactions. The most common reported adverse events associated with panitumumab were skin toxicities, fatigue, abdominal pain, nausea and diarrhea. Grade 3 or 4 hypomagnesemia was observed in eight percent (7/88) and 12 percent (11/91) of patients, respectively.

AMG 706 in Thyroid Cancer

Data were also presented from a subset analysis of seven patients with advanced thyroid cancer enrolled in a Phase 1 dose-finding study evaluating AMG 706 in patients with refractory solid tumors. The data suggested that AMG 706 has promising antitumor activity in thyroid cancer, with three patients achieving a partial response. The most frequently reported Grade 3 adverse events were diarrhea, hypertension, fatigue and vomiting. There were no Grade 4 events reported. Based on these favorable findings, a Phase 2 study of AMG 706 for the treatment of advanced thyroid cancer was initiated in 2005. Currently, the Phase 2 study is fully enrolled, and treatment is ongoing (Abstract #3030).

About Panitumumab

Panitumumab is an investigational 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 XenoMouse(R) 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 and humanized antibodies as foreign and may launch an immune response. The goal of developing fully human monoclonal antibodies is to offer effective targeted therapies with minimum risk of immune response against these agents.

Panitumumab received Fast Track designation from the U.S. Food and Drug Administration (FDA) in July 2005 for patients with metastatic colorectal cancer who have failed standard chemotherapy regimens. It 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 head and neck. In March 2006, Amgen announced completion of the Biologic License Application (BLA) submission with the FDA for panitumumab. The potential indication is for the treatment of metastatic colorectal cancer in patients who have failed prior chemotherapy, including oxaliplatin and/or irinotecan containing regimens. In April 2006, marketing applications were simultaneously submitted to the European Medicines Agency (EMEA) and Health Canada and in May 2006 in Australia and Switzerland.

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 and survival of the cancer cell.

About AMG 706

AMG 706 is an investigational, oral molecule designed to target members of a family of proteins called tyrosine kinases. Tyrosine kinases play important roles in controlling many cellular functions, including cell growth. Alteration in the normal functions of tyrosine kinases is strongly associated with cancer development and tumor growth.

By targeting tyrosine kinases in cancer patients, AMG 706 may provide anticancer activity against two important biological processes known to be critical in cancer growth: angiogenesis (the growth of new blood vessels) and cancer cell signaling. AMG 706 is believed to inhibit the activity of all three receptors in the Vascular Endothelial Growth Factor receptor (VEGFr) family that are the main drivers of angiogenesis. AMG 706 may also selectively inhibit Platelet-Derived Growth Factor receptor (PDGFr) and Kit, tyrosine kinases that are important in stimulating tumor cell growth and proliferation. These attributes are being evaluated in clinical trials.

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. 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.

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.

SOURCE: Amgen Inc.

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