

# AMG 706 Shows Activity in Phase 2 Study of Patients with Advanced Imatinib-Resistant Gastrointestinal Stromal Tumors

November 4, 2006

### **Broad Clinical Development Program for AMG 706 Under Way**

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Nov. 4, 2006--Amgen (NASDAQ:AMGN) today announced results from a multicenter, single-arm, Phase 2 study of AMG 706, an investigational oral targeted VEGF receptor inhibitor. In this study, AMG 706 showed encouraging clinical activity in patients with advanced high-dose imatinib-resistant gastrointestinal stromal tumors (GIST). These data were presented in an oral session at the Connective Tissue Oncology Society (CTOS) meeting in Venice, Italy.

"AMG 706 targets tyrosine kinases, a family of proteins thought to play an important role in controlling cell development and tumor growth," said Robert Benjamin, M.D. Chair, Sarcoma Medical Oncology Professor, MD Anderson Cancer Center. "This study evaluated the safety and efficacy of AMG 706 given for at least eight weeks to patients whose disease progressed or relapsed while receiving imatinib. Based on these encouraging findings, we believe that further study of AMG 706 is warranted."

One hundred thirty-eight patients received at least one dose of AMG 706. Patients received 125mg per day orally until progressive disease or toxicity. Independent central radiographic review confirmed 120 patients as protocol eligible. Responses were measured by RECIST, fluorodeoxyglucose -positron emission tomography (FDG-PET) and Choi criteria (defined as a 10 percent decrease in tumor size or a 15 percent decrease in tumor density by contrast-enhanced computed tomography scan).

The primary endpoint of the trial was objective response per RECIST assessed by an independent review. Secondary efficacy endpoints included an assessment of AMG 706 on duration of response, progression-free survival, time to progression, survival and adverse events. Additional secondary endpoints explored the utility of FDG-PET, target tumor size/density changes and assessed the pharmacokinetics of AMG 706.

The RECIST assessment of the 120 evaluable patients showed a clinical benefit rate of 27 percent (three percent partial response plus 24 percent durable stable disease greater than or equal to 22 weeks). At week eight, 23 percent of patients demonstrated an objective response by FDG-PET (28/120) and 33 percent showed an objective response by Choi criteria (39/120). The median progression-free survival was 16 weeks, with 26 week progression-free survival of 27 percent. Median survival was 59 weeks.

Treatment-related adverse events that occurred in 15 percent or more of all patients were: diarrhea (55 percent), hypertension (48 percent), fatigue (45 percent), headache (47 percent) and nausea (35 percent).

### About VEGF

The VEGF pathway plays a central role in tumor angiogenesis (the process of developing new blood vessels) with the VEGFr1-2 pathway driving angiogenesis and VEGFr3 driving lymphangiogenesis (the formation of lymphatic vessels from pre-existing lymphatic vessels, in a method believed to be similar to angiogenesis). Targeting the entire VEGF pathway may potentially lead to improved control of angiogenesis in cancer.

# About AMG 706

AMG 706 is an oral, highly selective inhibitor of the VEGF pathway, targeting all of the VEGF receptors that demonstrate both antiangiogenic and direct antitumor activity (including inhibition of Platelet Derived Growth Factor receptor and Kit, two proteins involved in the regulation of cell proliferation). AMG 706 demonstrated the ability to induce objective responses and prolonged stable disease in phase 1 trials of heavily pre-treated patients with a variety of small tumors. The results of the phase 1 trials have led to the initiation of a broad clinical program in a variety of solid tumors including breast and non-small lung cancer, and that will document the utility of AMG 706 both as a monotherapy and in combination with commonly used therapies. AMG 706 is also being evaluated as a monotherapy in refractory differentiated or medullary thyroid cancer, where there exist no effective therapeutic options.

## 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 quarantee 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 result 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.

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SOURCE: Amgen