FDA Grants Fast Track Designation for Amgen's AMG 531 and AMG 706 Experimental Therapies to Potentially Treat Life-Threatening Conditions

December 6, 2004

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Dec. 6, 2004--Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has granted fast track designation for two of the company's experimental therapies, AMG 531 and AMG 706. AMG 531 received orphan drug designation in 2003.

"AMG 531 is Amgen's first peptibody and represents a new approach to potentially treat immune thrombocytopenic purpura (ITP), an autoimmune bleeding disorder. AMG 706, Amgen's first investigational oral cancer therapy, may hold promise for various tumor types and is currently in Phase 2 trials for the treatment of imatinib-resistant gastrointestinal stromal tumors (GIST), a fatal cancer," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development at Amgen. "Fast track designation represents an important step for both of these molecules and will help to streamline development."

Under the FDA Modernization Act of 1997, fast track designation allows the FDA to accept, on a rolling basis, portions of a marketing application for review prior to the completion of the final registrational package. Fast track designation may potentially expedite the review of a drug that is intended for the treatment of a serious life-threatening condition and demonstrates the potential to address an unmet medical need for such a condition. The FDA orphan drug designation provides marketing exclusivity incentives to companies that develop drugs for diseases affecting less than 200,000 people in the United States.

The Use of AMG 531 in Immune Thrombocytopenia Purpura (ITP)

About Immune Thrombocytopenia Purpura (ITP)

Immune (idiopathic) thrombocytopenia purpura (ITP) is an autoimmune bleeding disorder characterized by low levels of platelets in the blood. ITP affects approximately 70,000 people in the U.S. Current treatment of ITP involves reducing platelet destruction with drugs (e.g., corticosteroids) that alter or suppress the immune system or with surgical removal of the spleen (splenectomy), where the antibody-tagged platelets are destroyed. Corticosteroids are associated with side effects such as weight gain, rash and exacerbation of diabetes and osteoporosis. Splenectomy and other therapies used to treat ITP that suppress or modulate the immune system can increase a patient's risk of infection. Since approximately 50 percent of patients do not respond to drug therapy and 40 percent of patients do not respond to splenectomy, new therapies for ITP are needed.

About AMG 531

As an investigational platelet growth factor, AMG 531 appears to directly stimulate platelet production and may offer physicians a way to shift the treatment focus from preventing platelet destruction to boosting platelet production in patients with ITP. AMG 531 is an engineered protein therapeutic developed by Amgen called a peptibody that provides targeted action -- in this case, on the thrombopoietin (TPO) receptor. Like TPO, AMG 531 binds to the TPO receptor and stimulates precursor or "parent" cells of platelets, called megakaryocytes, to mature into platelets.

In Phase 1 and 2 clinical studies recently reported at the 46th Annual American Society of Hematology (ASH) meeting, AMG 531 appeared to enhance platelet production in patients diagnosed with ITP. AMG 531 has been generally well tolerated. The most frequently reported adverse events were bruising, nosebleeds, headache and mouth blisters.

The Use of AMG 706 in Imatinib-Resistant Gastrointestinal Stromal Tumors (GIST)

About Gastrointestinal Stromal Tumors (GIST)

Gastrointestinal stromal tumors (GISTs) belong to a group of cancers called soft tissue sarcomas. Sarcomas are a rare type of cancer that can occur in connective tissues, bones, muscles, fat, nerves, blood vessels and cartilage. GISTs start in the wall of the stomach, small and large intestine and affect approximately 5,000 to 10,000 Americans annually. Since GIST are resistant to traditional treatments such as chemotherapy and radiation, surgery is considered the best way to initially treat GIST. However, many tumors cannot be surgically removed because they are too large or have already spread to other parts of the body before diagnosis. Since its approval in 2002, imatinib has been the mainstay of therapy for advanced or metastatic GIST. However, no approved therapies exist for GIST patients that no longer respond to imatinib.

About AMG 706

AMG 706 is an oral multi-kinase inhibitor (MKI) that works by selectively targeting all known vascular endothelial growth factors (VEGF), platelet derived growth factor (PDGF), Kit and Ret receptors. Through the combined action of Kit and PDGF receptor inhibition, coupled with potent VEGF receptor inhibition, AMG 706 potentially may provide more than one mechanism of action in various cancers. Activating mutations of Kit or PDGF receptors are critical to the pathogenesis of more than 90 percent of GIST.

Early clinical data show signs of tumor regression with promising preliminary safety data that may potentially allow for combination therapy. AMG 706 is being evaluated as both a monotherapy and in combination with other agents for the treatment of various cancers, including imatinib-resistant GIST, non-small cell lung cancer and colorectal cancer.

Patients and physicians can access www.amgentrials.com for more information about ongoing AMG 531 and AMG 706 clinical trials.

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.

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 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 U.S. Food and Drug Administration (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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