



## Updated Interim Long-Term Follow-up Data Reported AMG 531 Dosed Once Weekly Increased and Sustained Platelet Counts in Patients with Immune Platelet Disorder

December 11, 2006

ORLANDO, Fla.--(BUSINESS WIRE)--Dec. 11, 2006--Amgen (NASDAQ: AMGN) today announced interim results from an open-label extension study showing that long-term administration (up to 48 weeks) of its investigational therapy AMG 531 stimulated platelet production and was generally well-tolerated in adult patients with immune thrombocytopenic purpura (ITP). These updated interim data were presented in an oral session at the American Society of Hematology (ASH) 48th Annual Meeting in Orlando, Fla. (Abstract # 476)

ITP is a chronic and potentially serious bleeding disorder caused by an immune system malfunction that mistakenly recognizes the body's own platelets as foreign and destroys them, as well as a decrease in platelet production, which results in low platelet counts. Platelets are specialized blood cells that help prevent and stop bleeding by participating in clotting. The risk of a bleeding event increases when platelet counts drop to less than 30,000 platelets per microliter.

"Unlike most current ITP treatments, which interfere with platelet destruction, AMG 531 is designed to increase the production of platelets at a rate that outpaces their destruction by the immune system," said David J. Kuter, M.D., D.Phil., director of Center for Hematology, Massachusetts General Hospital, Boston. "This study now includes two years of follow-up data and the interim results at 48 weeks are encouraging. Individualized dosing of AMG 531 may provide a new option for patients with ITP, potentially allowing tapering off of steroid therapy."

The long-term follow-up study has been ongoing for more than two years and is open to patients who have completed a previous AMG 531 study. To date, 104 patients have been enrolled. This planned interim analysis at 48 weeks includes 36 patients, who previously completed a Phase 2 trial, with AMG 531. Overall, 86 percent of patients (n=31) achieved a platelet response, defined as achieving platelet count of at least 50,000 platelets per microliter of blood and doubling of their baseline. At 48 weeks, more than 57 percent of patients still on study (n=23) had maintained this platelet response. The median time to first response was three weeks and the mean dose at first response was 3.4 ug/kg.

Thirty patients had undergone splenectomy prior to study enrollment and nine were receiving concurrent corticosteroids, which were able to be tapered when platelet counts reached greater than 50,000 platelets per microliter of blood. Of the nine patients on concurrent corticosteroids, 67 percent (n=6) discontinued corticosteroid treatment and 11 percent (n=1) had at least a 25 percent corticosteroid dose reduction.

In this study, AMG 531 appeared generally well-tolerated. The most frequently reported adverse events were headache, upper respiratory infection and fatigue. Four patients experienced serious treatment-related adverse events, including bone pain, vaginal hemorrhage/anemia, transverse sinus thrombosis, and reversible increased bone marrow reticulin (reported as myelofibrosis). No neutralizing antibodies have been detected to date.

### About the Study

This ongoing, open-label extension study is assessing the safety and efficacy of long-term administration of AMG 531 in both pre- and post-splenectomy ITP patients. Eligible patients have completed a previous AMG 531 study in ITP, including those from two recent Phase 3 AMG 531 studies in ITP, and have a baseline platelet count of less than 50,000 platelets per microliter, with no recent significant change in medical history. The AMG 531 starting dose was 1 ug/kg by subcutaneous injection with dose adjustment to a maximum of 15 ug/kg. Patients were administered AMG 531 by injection once weekly unless their platelet count exceeded 400,000 platelets per microliter. Concurrent corticosteroid treatment could be tapered when patients' platelet counts reached 50,000 platelets per microliter. Data for patients previously enrolled in the Phase 3 trials are still blinded.

For further information on AMG 531 clinical trials, please visit [www.amgentrials.com](http://www.amgentrials.com).

### About AMG 531

AMG 531 is an investigational thrombopoiesis-stimulating protein ("peptibody") that contains two component regions. Peptibodies are engineered therapeutic molecules that can bind to human drug targets and contain peptides linked to the constant domains of antibodies. AMG 531 works similarly to thrombopoietin (TPO), a natural protein in the body. The active peptide component stimulates the TPO receptor, which is necessary for growth and maturation of bone marrow cells and plays a very important role in platelet production. In 2004, the U.S. Food and Drug Administration (FDA) granted fast track designation for AMG 531. Orphan designation for ITP was granted in 2003 by the FDA and in 2005 by the European Agency for the Evaluation of Medicinal Products (EMEA).

### About ITP

Immune (idiopathic) thrombocytopenic purpura (ITP) is a chronic and potentially serious autoimmune bleeding disorder characterized by low levels of platelets in the blood, a condition known as thrombocytopenia. A normal platelet range for a person without ITP is 150,000 - 400,000 platelets per microliter of blood. The risk of a bleeding event increases when platelet counts drop to less than 30,000 platelets per microliter.

With ITP, platelets are destroyed by the patient's own immune system. ITP has historically been considered a disease of platelet destruction; however, recent data also suggest that the body's natural platelet production processes are unable to compensate for low levels of platelets in the blood. Increasing the rate of platelet production may address low platelet levels associated with ITP.

According to the Platelet Disorder Support Association, approximately 200,000 Americans have been diagnosed with ITP. Additionally, in the United States and Europe combined, ITP is estimated to affect 50 to 100 new persons per million annually.

### 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 deep and broad 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](http://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](http://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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