Interim Long-Term Follow-up Data Show AMG 531 Increases Platelets in Patients with Immune Thrombocytopenic Purpura; Results Suggest Once-Weekly Dosing of AMG 531 Results in Sustained Platelet Response

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ATLANTA--(BUSINESS WIRE)--Dec. 12, 2005--Amgen (NASDAQ:AMGN), the world's largest biotechnology company, today announced interim results from an open-label study showing that long-term administration (up to 48 weeks) of its investigational therapy AMG 531 was generally well-tolerated and stimulated platelet production in patients with immune thrombocytopenic purpura (ITP). Overall, 85 percent of patients in the study (29 of 34) achieved a platelet response, defined as doubling of the baseline platelet count and at least 50,000 platelets per microliter of blood. The data were presented during an oral presentation at the American Society of Hematology (ASH) 47th Annual Meeting and Exposition. (Abstract #220)

ITP is characterized by an immune system malfunction that recognizes the body's own platelets as foreign and destroys them, potentially resulting in dangerously low platelet counts (less than 30,000 platelets per microliter). Platelets are specialized blood cells that help prevent and stop bleeding by participating in clotting. Normal platelet range for a person without ITP is 150,000 to 400,000 platelets per microliter. AMG 531 is being investigated as a new approach to treat ITP, and other platelet deficiencies, by directly increasing platelet production to outpace platelet destruction by the immune system.

"Traditional therapies for ITP have focused on diminishing platelet destruction by suppressing the immune system, beginning with the use of steroids, followed by surgical removal of the spleen and more intensive immunosuppression. These treatments have potentially serious side effects. For ITP patients who do not respond to these therapies, there are no effective treatment options," said James George, M.D., professor of medicine at the University of Oklahoma Health Sciences Center, Oklahoma City. "The long-term study results show that AMG 531 administered as an individualized weekly dose resulted in a durable platelet response. If approved, AMG 531 may provide an important therapeutic option for ITP patients, potentially enabling patients to taper off long-term steroid therapy."

Interim results were presented for 34 patients treated with AMG 531 for up to 48 weeks. Twenty-eight patients had undergone splenectomy before study entry and eight were receiving concurrent corticosteroids for ITP. Overall, 47 percent of patients (n=16) had a durable platelet response, defined as platelet response at six or more weeks between weeks 18 through 25. Of the eight patients on concurrent corticosteroids, 50 percent (n=4) discontinued corticosteroid treatment and 25 percent (n=2) had at least a 50 percent dose reduction.

"It is exciting that most patients in this study achieved platelet counts of greater than 50,000 per microliter, despite how refractory they were, from a starting count of approximately 18,000," said James B. Bussel, M.D., professor of pediatrics and medicine at the Weill Cornell Medical Center, New York, NY. "This is important because it suggests that AMG 531 may stimulate platelet production faster than the immune system can destroy them, enabling patients to sustain a satisfactory platelet count with ongoing AMG 531 treatment."

In this study, AMG 531 was generally well-tolerated. The most frequently reported adverse events were headache, upper respiratory infection and fatigue. Serious adverse events reported as treatment related include bone pain (n=1); anemia (n=1); and vaginal hemorrhage (n=1). Additionally, there was one reported case of diffuse reticulin formation in the bone marrow reported as myelofibrosis. Reticulin formation is hypothesized as due to excessive accumulation of megakaryocytes in the bone marrow. Follow-up bone marrow biopsies reveal that the reticulin is improving. 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 had completed a previous AMG 531 study in ITP and had 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. Once patients reached a stable dose and schedule, physician office visits were reduced from weekly to once per month. Concurrent corticosteroid treatment could be tapered when patients' platelet counts reached 50,000 platelets per microliter. The study is available for patients completing the two ongoing Phase 3 AMG 531 studies in ITP.

For further information on AMG 531 clinical trials, please visit www.amgentrials.com.

About AMG 531

AMG 531 is a first-in-class investigational protein called a peptibody, which contains two component regions. AMG 531 works similarly to thrombopoietin (TPO), a natural protein in the body. The active peptide component of AMG 531 stimulates the TPO receptor, or "on-off switch," which is necessary for growth and maturation of bone marrow cells and plays a very important role in platelet production. The carrier component contains a portion of natural immunoglobulin called the constant or Fc component, which increases the half-life of AMG 531. In 2004, the U.S. Food and Drug Administration (FDA) granted fast track designation for AMG 531. Phase 3 clinical trials for ITP were initiated in 2005.

About Immune Thrombocytopenic Purpura

ITP is a serious, chronic autoimmune bleeding disorder characterized by low levels of platelets in the blood (less than 30,000 platelets per microliter). Platelets, also called thrombocytes, are specialized blood cells that help prevent and stop bleeding by participating in clotting. With ITP, platelets are destroyed by the patient's own immune system - in effect, it is a "disease of platelet destruction." The low platelet levels in ITP increase the potential for bleeding and decrease the ability for blood to clot, resulting in bruising ("purpura") and bleeding. In extreme cases death can occur due to an intracerebral hemorrhage or bleeding into the brain. According to the Platelet Disorder Support Association, the number of Americans with ITP has been estimated to be approximately 200,000. Of those who are diagnosed, only half receive treatment. ITP affects about three times as many women as men.

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.

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, 2004, 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.

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