Pivotal Phase 3 Romiplostim Study in Splenectomized Patients Meets Primary Endpoints

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Data Show Romiplostim Increased and Sustained Platelet Counts in Splenectomized Adult Patients with Immune Thrombocytopenic Purpura

ATLANTA--(BUSINESS WIRE)--Dec. 8, 2007--Amgen Inc. (NASDAQ:AMGN) today announced results from a randomized, pivotal Phase 3 study that showed romiplostim (AMG 531) increased and sustained platelet counts in splenectomized (spleen removed) adult patients with chronic Immune Thrombocytopenic Purpura (ITP). Additionally, romiplostim-treated patients taking concurrent ITP medications such as corticosteroids were able to reduce or discontinue these medications. Adult ITP is a serious chronic autoimmune disorder characterized by low platelet counts in the blood, a condition known as thrombocytopenia. These Phase 3 data will be presented in a Plenary Session at the American Society of Hematology (ASH) 49th Annual Meeting in Atlanta, GA (Abstract #2).

"The majority of available therapies for ITP decrease platelet destruction by the immune system, but we have been aware for some time that inadequate platelet production is also a problem in this disorder. Romiplostim is an investigational therapy that stimulates platelet production in a manner similar to the body's natural hormone thrombopoietin, and is currently being evaluated for it's ability to increase the platelet count by increasing platelet production in ITP," said Dr. Terry Gernsheimer, Associate Professor of Medicine, Division of Hematology, University of Washington School of Medicine, and the Puget Sound Blood Center. "The encouraging results of this study highlight the potential of this new therapeutic approach to the treatment of adult patients with chronic ITP."

Adult ITP is a chronic and serious disorder caused by a deregulated immune system that mistakenly destroys the body's own platelets and impairs 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 bleeding events increases as platelet counts decrease, especially as they go below 30,000 platelets per microliter.

Amgen has recently filed for regulatory approval of romiplostim for use in the treatment of thrombocytopenia in adults with chronic ITP in the United States (U.S.), European Union (EU), Australia and Canada. Regulatory authorities in Australia and Canada have granted priority review of Amgen's application.

Efficacy and safety data from another pivotal Phase 3 study evaluating romiplostim in non-splenectomized chronic ITP patients as well as interim results from a long-term extension study in chronic adult ITP will be presented on Monday, Dec. 10, 2007 (Abstracts #565 and 568).

This Phase 3 study met its primary endpoint with 38.1 percent of romiplostim-treated patients (n=42) achieving durable platelet response compared to none of the patients receiving placebo (n=21, p=0.0013). Durable platelet response was defined as a weekly platelet count of greater than or equal to 50,000 platelets per microliter for greater than six of the final eight study weeks. Additionally, no rescue medications (defined as any additional ITP medicine needed to increase platelet counts) were administered at any time during the study to patients achieving durable platelet response.

Overall platelet response was 78.6 percent in romiplostim-treated patients compared to no response in the placebo group (p less than 0.0001). Overall platelet response was defined as either transient platelet response (greater than or equal to four weekly platelet responses, separated by greater than 8 weeks from administration of any rescue medication) or durable platelet response. The mean number of weeks with a platelet response was significantly greater in romiplostim-treated patients than in the placebo group (12.3 weeks vs. 0.2 week, p less than 0.0001).

Romiplostim-treated patients receiving concurrent ITP medications (n=12/12) discontinued or reduced use of such medications compared to 16.7 percent of placebo-treated patients (n=1/6). Across the study, 26.2 percent of romiplostim-treated patients required rescue medications compared to 57.1 percent of those in the placebo group (p=0.0175).

Two serious treatment-related adverse events were reported in the romiplostim group. In one patient, elevated bone marrow reticulin that returned to baseline three months after withdrawal of romiplostim was reported. Another patient experienced thrombosis that was successfully treated, allowing study continuation. The most commonly reported adverse events in the romiplostim group included myalgia, dizziness, pharyngolaryngeal pain, pyrexia, arthralgia, insomnia, and diarrhea. Serious bleeding adverse events (greater than or equal to Grade 3) were reported in patients in both the romiplostim (n=4/42, 9.5 percent) and placebo (n=4/21, 19 percent) groups, all occurring at platelet counts below 30,000 per microliter. No patient developed neutralizing antibodies against either romiplostim or endogenous TPO.

About the Phase 3 Study

This randomized, double-blind, placebo controlled, Phase 3 study assessed the efficacy and safety of romiplostim in splenectomized adults with chronic ITP. Sixty-three splenectomized patients were enrolled (placebo, 21; romiplostim, 42) with a median age of 51 years (range 26-88) and a mean baseline platelet count of 13,500 platelets per microliter. These patients continued to have low platelet counts after a median of 7.75 years of having chronic ITP and more than five prior ITP treatments, including splenectomy. The romiplostim starting dose was 1 ug/kg by subcutaneous injection and was adjusted based on weekly platelet response.

About Romiplostim

Romiplostim is an investigational thrombopoiesis-stimulating Fc-peptide fusion 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. Romiplostim works similarly to thrombopoietin (TPO), a natural protein in the body. Romiplostim stimulates the TPO receptor, which is necessary for growth and maturation of bone marrow cells and plays a very important role in platelet sustaining platelet counts. In 2004, the U.S. Food and Drug Administration (FDA) granted fast track designation for romiplostim. Romiplostim has received orphan designation for this proposed indication in four major global regions, including the U.S. (2003); the EU and Switzerland (2005); and Japan (2006).

About Adult ITP

Adult Immune (idiopathic) thrombocytopenic purpura (ITP) is a chronic and serious autoimmune 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, U.S. 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.

Forward Looking Statement

This news release contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Dec. 8, 2007 and expressly disclaims any duty to update information contained in this news release.

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 safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products are affected by the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' 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 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.

CONTACT: Amgen, Thousand Oaks
Christine Regan: 617-359-1324 (media)
Arvind Sood: 805-447-1060 (investors)

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