Pivotal Phase 3 Nplate(TM) Study in Non-Splenectomized Patients Met Primary Endpoints

December 10, 2007

Data Also Shows Potential of Nplate as a Long-term Treatment Option for Chronic Adult Immune Thrombocytopenia Purpura

ATLANTA--(BUSINESS WIRE)--Dec. 10, 2007--Amgen Inc. (NASDAQ:AMGN) today announced results from a second randomized, pivotal Phase 3 study where Nplate(TM) (romiplostim) increased and sustained platelet counts in non-splenectomized (spleen not removed) adult patients with chronic Immune Thrombocytopenic Purpura (ITP). Additionally, Nplate-treated patients taking concurrent ITP medications such as corticosteroids were able to reduce or discontinue these medications. Adult ITP is a chronic and serious autoimmune disorder characterized by low platelet counts in the blood, a condition known as thrombocytopenia. These Phase 3 data were presented today in an oral session at the 49th American Society of Hematology Annual Meeting (ASH) in Atlanta, Georgia (Abstract #565).

"Patients without a splenectomy, or for whom this surgical procedure is not an option, often require treatment with corticosteroids or immunoglobulin therapy," said David J. Kuter, M.D., D. Phil., Chief of Hematology, Massachusetts General Hospital, Boston. "This six month study is encouraging in that most Nplate-treated patients were able to decrease or stop such treatment."

Additional data presented today in an oral session included updated interim results from an ongoing, open-label extension study evaluating extended treatment (up to 122 weeks of patient follow-up) with Nplate on platelet counts in adult patients with chronic ITP (Abstract #568).

Efficacy and safety data from another pivotal Phase 3 study evaluating Nplate in splenectomized chronic adult ITP patients were presented yesterday in a Plenary Session (Abstract #2).

Nplate 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 central role in increasing platelet counts.

Randomized Phase 3 Study of Nplate in Non-Splenectomized Patients (Abstract #565)

This Phase 3 study met its primary endpoint with 61 percent of Nplate-treated patients (n=41) achieving durable platelet response compared to 4.8 percent of patients receiving placebo (n=21). 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 in the study patients achieving a durable response (p less than 0.0001).

Overall response was 87.8 percent in Nplate-treated patients as compared to 14.3 percent of patients 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 rescue therapy) or durable platelet response. The mean number of weeks with a platelet response was significantly greater in Nplate-treated patients than in the placebo group (15.2 weeks vs. 1.3 weeks). Across the study, 17.1 percent of the Nplate-treated patients required rescue medications compared to 61.9 percent of placebo-treated patients (p=0.0004).

Five serious adverse events were reported, none of which were deemed treatment-related. The most commonly reported adverse events in the Nplate group included myalgia, dizziness, pharyngolaryngeal pain, pyrexia, arthralgia, insomnia, and diarrhea. No patients tested positive for neutralizing antibodies against either Nplate or endogenous TPO protein.

The randomized, double-blind, placebo-controlled Phase 3 study was designed to evaluate the efficacy and safety of Nplate to increase and sustain platelet counts in adult patients with chronic ITP. The Nplate starting dose was 1 ug/kg by subcutaneous injection and was adjusted based on weekly platelet response.

Amgen has filed for regulatory approval of Nplate 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 the U.S., Australia and Canada have granted priority review of Amgen's application.

Nplate Extension-Study (Abstract #568)

An updated interim analysis from an ongoing, open-label extension study (n=136 patients) showed that the majority (range 50-75 percent) of Nplate-treated patients achieved long-term platelet response. Response was defined as a weekly platelet count of greater than or equal to 50,000 platelets per microliter, and doubling of the baseline platelet count. The longest treatment duration was greater than 120 weeks (n=2), and the shortest treatment duration was greater than 24 weeks (n=89). At the time of analysis, 20 patients had been followed for 96 weeks or longer. Of the 30 patients on concurrent corticosteroids at study entry, 63 percent were able to discontinue or reduce their corticosteroid treatment through the course of the trial. The use of rescue medications was decreased from 24 percent during weeks 1-12 of study to 6 percent during weeks 109-120 of the study.

"Currently, Nplate is the only thrombopoietic ITP treatment for which there are over two years of follow-up data," said James Bussel, M.D., director of Platelet Research, Weill Medical College, Cornell University, New York. "This latest interim analysis is promising for the potential of Nplate as a treatment for adult patients with chronic ITP."

In this study, Nplate appeared generally well-tolerated and adverse events did not increase in frequency during the course of the trial. The five most frequently reported adverse events were headache (31 percent), contusion (27 percent), fatigue (24 percent), diarrhea (24 percent) and epistaxis (23 percent). Eleven patients experienced serious treatment-related adverse events, of which three patients were withdrawn from the study due to vaginal hemorrhage, reversible increased bone marrow reticulin (reported as myelofibrosis), and monoclonal gammopathy of undetermined significance (MGUS), initially reported as multiple myeloma). To date, one patient developed a neutralizing antibody to Nplate; however, it was absent upon re-testing four months after Nplate treatment was stopped.

This ongoing, open-label extension study is assessing the safety and efficacy of long-term administration of Nplate in both non-splenectomized and splenectomized adult chronic ITP patients. Eligible patients had completed a previous ITP Nplate study, and had a baseline platelet count of less than 50,000 platelets per microliter, with no significant change in medical history. The Nplate starting dose was 1 ug/kg by subcutaneous injection and was adjusted based on weekly platelet response. Patients were administered Nplate by injection once weekly unless their platelet count exceeded 400,000 platelets per microliter. Concurrent corticosteroid treatment could be tapered when patients' platelet counts were above 50,000 platelets per microliter.

About Nplate (Romiplostim)

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

About Adult ITP

Adult Immune (idiopathic) thrombocytopenic purpura (ITP) is a chronic and potentially serious autoimmune disorder characterized by low platelet counts 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 platelet counts in the blood. Increasing the rate of platelet production may address low platelet counts associated with ITP.

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. 10, 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)

SOURCE: Amgen Inc.