Long-term Follow Up Interim Data Show Nplate(TM) Increased and Sustained Platelet Counts in Adult Chronic ITP Patients

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Interim Phase 2 MDS Data Also Presented at ASH Annual Meeting

SAN FRANCISCO, Dec 08, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Amgen Inc. (Nasdaq: AMGN) today released updated results from the ongoing, open-label extension study of the long-term safety and efficacy of Nplate(TM) (romiplostim) in adult patients with chronic immune thrombocytopenic purpura (ITP). Chronic ITP is a chronic and serious autoimmune disorder characterized by lower than expected platelet counts in the blood, sometimes leading to serious bleeding events. The results were presented today as an oral presentation at the 50th Annual Meeting of the American Society of Hematology (ASH Abstract # 402). Results from a study of Nplate in myelodysplastic syndromes (MDS) also were presented.

"These data show Nplate increased platelet counts in most patients for most of the time, and clinically relevant bleeding was reduced over time," said David J. Kuter, M.D., Chief of Hematology, Massachusetts General Hospital, Boston. "This is significant because Nplate can be a long-term treatment for adult chronic ITP patients, who are at risk of serious bleeding events if their platelet counts drop to less than 30,000 per microliter. These patients have had limited availability to long term treatment options."

These study results showed that overall 74 percent of patients (160/215) achieved a platelet response defined as a platelet count of 50,000 platelets per microliter and doubling of the baseline platelet count (median:17,000 platelets per microliter). A platelet response was achieved by 30 percent (61/207) of patients after the first dose and by 47 percent (94/199) of patients after the third dose. The average treatment period was 76 weeks and the longest duration of treatment was 204 weeks.

Additional key findings from the Extension study show:

-- Platelet counts increased: Platelet counts of Nplate-treated patients were increased from baseline by 20,000 platelets per microliter more than 80 percent of the time in 47 percent of patients and more than half the time in 67 percent of patients.

-- Platelet counts maintained: Platelet count increases of 50,000 platelets per microliter were sustained for greater than or equal to 10, greater than or equal to 25, and greater than or equal to 52 consecutive weeks in 77 percent (127/164), 67 percent (95/141), and 41 percent (48/116) of patients, respectively.

In this study, adverse events (AEs) did not increase with time and were reported in 86 percent of patients, with most mild to moderate in severity. The most common were headache (34 percent), contusion (32 percent), and fatigue (31 percent). Treatment-related and serious AEs were reported in 28 percent and 29 percent of patients, respectively. Treatment-related serious AEs were reported in 7 percent of patients. Five percent of patients (11/215) discontinued treatment due to AEs.

Bone marrow reticulin was present or increased in eight patients with no evidence of progression to collagen fibrosis or chronic idiopathic myelofibrosis. Thrombotic/thromboembolic events were reported in seven patients, of whom six had pre-existing risk factors. To date, one patient developed a neutralizing antibody to Nplate; however, it did not cross react with thrombopoietin and it was absent upon re-testing four months after Nplate treatment was stopped.

This ongoing, open-label study is assessing the safety and efficacy of long-term administration of Nplate in both splenectomized and non-splenectomized adult chronic ITP patients. As of July 2008, 223 patients had enrolled and 215 were treated with Nplate. Sixty-one percent of patients were female and, of the enrolled patients, 44 percent had undergone a splenectomy (removal of the spleen).

Eligible patients had completed a previous ITP Nplate study, with no significant change in medical history. The Nplate starting dose was 1 ug/kg by subcutaneous injection and was adjusted to maintain a platelet count between 50,000 and 200,000 platelets per microliter.

Interim Phase 2 Nplate MDS Data Also Presented (Abstract # 224)

Interim data from an ongoing Phase 2 multicenter, randomized, double-blind, placebo-controlled study evaluating Nplate in patients with low or intermediate risk MDS receiving azacytidine were also presented (n=40). The interim analysis showed that Nplate reduced the incidence of clinically significant, treatment-related thrombocytopenic events and platelet transfusions. Nplate also improved the platelet nadir, defined as the lowest peripheral blood count that occurs secondary to bone marrow suppression, in MDS patients receiving azacytidine.

Each study arm was in combination with azacytidine, and serious AEs were observed in 77 percent of the placebo group, 46 percent of the Nplate 500ug group and 71 percent of the 750ug group. One incident of each of the following events was reported: arthralgia, rash, hypersensitivity, pulmonary hemorrhage, hemorrhage and epistaxis. Two patients in the placebo group died, one of fungal pneumonia and the other of pulmonary hemorrhage. One case of disease progression from MDS to acute myeloid leukemia was observed in the Nplate 500ug treated group.

About Adult ITP

In patients with ITP, platelets -- or blood cells needed to prevent bleeding -- are destroyed by the patient's own immune system. Low platelet counts leave adult ITP patients open to sudden serious bleeding events, making it impossible to arrest blood flow. The risk for serious bleeding events increases when platelet counts drop to less than 30,000 platelets per microliter; normal counts range from 150,000 to 400,000 platelets per microliter. ITP has historically been considered a disease of only platelet destruction although recent data suggest that the body's natural platelet production processes in ITP are also 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.

Currently available treatments (i.e., corticosteroids, immunglobulins) have limited application due to poor tolerability or transient effects. Surgical therapy (removal of the spleen) is also available to adult patients with chronic ITP, but does not work in all cases. Currently, there are 140,000 treated chronic ITP patients in Europe and the United States (U.S.). ITP affects about twice as many adult women as men.

About Myelodysplastic Syndromes

MDS is a disorder in which the production of blood cells by the bone marrow is disrupted and loses its ability to produce normal cells. There is no curative treatment for MDS, with the exception of bone marrow transplantation, and roughly 70 percent of all patients with MDS encounter complications or progression due to acute myeloid leukemia. MDS affects all ages, from children to adults, with the highest prevalence in those over sixty years of age.

Nplate is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than chronic ITP.

About Nplate

Nplate, Amgen's first peptibody, is a novel engineered therapeutic fusion protein with attributes of both peptides and antibodies, but is distinct from each. 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 that produce platelets.

Nplate was granted approval for the treatment of adult chronic ITP by the regulatory bodies in Australia in July and the U.S. in August 2008. In November 2008, the European Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending marketing authorization of Nplate in the European Union (EU). Amgen has also filed for regulatory approval of Nplate in Canada and Switzerland, and these applications are currently under review. Nplate has received orphan designation for ITP in the U.S. (2003), EU (2005), Switzerland (2005) and Japan (2006).

Nplate is indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts.

Important Safety Information

Serious adverse reactions associated with Nplate in clinical studies were bone marrow reticulin deposition and worsening thrombocytopenia after Nplate discontinuation.

Bone Marrow Reticulin Formation and Risk for Bone Marrow Fibrosis

-- Nplate administration increases the risk for development or progression of reticulin fiber deposition within the bone marrow.

-- In clinical studies, Nplate was discontinued in four of the 271 patients because of bone marrow reticulin deposition. Six additional patients had reticulin observed upon bone marrow biopsy. All 10 patients with bone marrow reticulin deposition had received Nplate doses greater than or equal to 5 mcg/kg, and 6 received doses greater than or equal to 10 mcg/kg.

-- Progression to marrow fibrosis with cytopenias was not reported in the controlled clinical studies. In the extension study, one patient with ITP and hemolytic anemia developed marrow fibrosis with collagen during Nplate therapy.

-- Clinical studies have not excluded a risk of bone marrow fibrosis with cytopenias.

-- Prior to initiation of Nplate examine the peripheral blood smear closely to establish a baseline level of cellular morphologic abnormalities. Following identification of a stable Nplate dose, examine peripheral blood smears and CBCs monthly for new or worsening morphological abnormalities (e.g., teardrop and nucleated red blood cells, immature white blood cells) or cytopenia(s).

-- If the patient develops new or worsening morphological abnormalities or cytopenia(s), discontinue treatment with Nplate and consider a bone marrow biopsy, including staining for fibrosis.

Worsened Thrombocytopenia After Cessation of Nplate

-- Discontinuation of Nplate may result in thrombocytopenia of greater severity than was present prior to Nplate therapy. This worsened thrombocytopenia may increase the patient's risk of bleeding, particularly if Nplate is discontinued while the patient is on anticoagulants or antiplatelet agents.

-- In clinical studies of patients with chronic ITP who had Nplate discontinued, four of 57 patients developed thrombocytopenia of greater severity than was present prior to Nplate therapy.

-- This worsened thrombocytopenia resolved within 14 days.

-- Following discontinuation of Nplate, obtain weekly CBCs, including platelet counts, for at least two weeks and consider alternative treatments for worsening thrombocytopenia, according to current treatment guidelines.

Thrombotic/Thromboembolic Complications

-- Thrombotic/thromboembolic complications may result from excessive increases in platelet counts. Excessive doses of Nplate or medication errors that result in excessive Nplate doses may increase platelet counts to a level that produces thrombotic/thromboembolic complications. In controlled clinical studies, the incidence of thrombotic/thromboembolic complications was similar between Nplate and placebo.

-- To minimize the risk for thrombotic/thromboembolic complications, do not use Nplate in an attempt to normalize platelet counts. Follow the dose adjustment guidelines to achieve and maintain a platelet count of greater than or equal to 50 x 10(9)/L.

Lack or Loss of Response to Nplate

-- Hyporesponsiveness or failure to maintain a platelet response with Nplate should prompt a search for causative factors, including neutralizing antibodies to Nplate or bone marrow fibrosis.

-- To detect antibody formation, submit blood samples to Amgen (1-800-772-6436). Amgen will assay these samples for antibodies to Nplate and thrombopoietin (TPO).

-- Discontinue Nplate if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the highest weekly dose of 10 mcg/kg.

Hematological Malignancies and Progression of Malignancy in Patients with a Pre-existing Hematological Malignancy or Myelodysplastic Syndromes (MDS)

-- Nplate stimulation of the TPO receptor on the surface of hematopoietic cells may increase the risk for hematologic malignancies. In controlled clinical studies among patients with chronic ITP, the incidence of hematologic malignancy was low and similar between Nplate and placebo.

-- In a separate single-arm clinical study of 44 patients with myelodysplastic syndromes (MDS), 11 patients were reported as having possible disease progression, among whom 4 patients had confirmation of acute myelogenous leukemia (AML) during follow-up.

-- Nplate is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than chronic ITP.

Laboratory Monitoring

-- Monitor CBCs, including platelet counts and peripheral blood smears, prior to initiation, throughout, and following discontinuation of Nplate therapy.

-- Prior to the initiation of Nplate, examine the peripheral blood differential to establish the baseline extent of red and white blood cell abnormalities.

-- Obtain CBCs, including platelet counts and peripheral blood smears, weekly during the dose adjustment phase of Nplate therapy and then monthly following establishment of a stable Nplate dose. Obtain CBCs, including platelet counts, weekly for at least 2 weeks following discontinuation of Nplate.

Nplate Distribution Program

-- Nplate is available only through a restricted distribution program called Nplate(TM) NEXUS (Network of Experts Understanding and Supporting Nplate(TM) and Patients) Program. Under the Nplate(TM) NEXUS Program, only prescribers and patients registered with the program are able to prescribe, administer, and receive Nplate. This program provides educational materials and a mechanism for the proper use of Nplate. To enroll in the Nplate(TM) NEXUS Program, call 1-877-NPLATE1 (1-877-675-2831).

General Safety

-- In the placebo-controlled studies, headache was the most commonly reported adverse drug reaction, occurring in 35 percent of patients receiving Nplate and 32 percent of patients receiving placebo. Headaches were usually of mild or moderate severity.

-- Most common adverse reactions (greater than or equal to 5 percent higher patient incidence in Nplate versus placebo) were Arthralgia (26 percent, 20 percent), Dizziness (17 percent, 0 percent), Insomnia (16 percent, 7 percent), Myalgia (14 percent, 2 percent), Pain in Extremity (13 percent, 5 percent) , Abdominal Pain (11 percent, 0 percent), Shoulder Pain (8 percent, 0 percent), Dyspepsia (7 percent, 0 percent), and Paresthesia (6 percent, 0 percent).

-- As with all therapeutic proteins, patients may develop antibodies to the therapeutic protein.

About Amgen

Amgen discovers, develops, manufactures 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 disorder, 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 http://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, 2008 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.

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