Pooled Phase 3 Study of Nplate(TM) (Romiplostim) in Adult Patients with Chronic ITP Published in The Lancet

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THOUSAND OAKS, Calif., Jan 31, 2008 (BUSINESS WIRE) -- Amgen Inc. (NASDAQ: AMGN) today announced data from two Phase 3 studies which evaluated the administration of Nplate(TM) (romiplostim) on increasing and sustaining platelet counts in both splenectomized (spleen removed) and non-splenectomized patients with chronic Immune Thrombocytopenic Purpura (ITP). The data will be published in the Feb. 2, 2008, issue of The Lancet.

"Adult ITP is a serious chronic autoimmune disorder characterized by low platelet counts in the blood, a condition known as thrombocytopenia," said study investigator David J. Kuter, M.D., D. Phil., Chief of Hematology, Massachusetts General Hospital, Boston. "These study findings are encouraging and provide hope that Nplate may provide physicians with a new therapeutic option for adult patients with chronic ITP."

The 24-week pooled study was comprised of two parallel Phase 3 trials and included 63 splenectomized patients and 62 non-splenectomized patients with ITP and a mean of three platelet counts of 30,000 per microliter or less. Patients were randomly assigned 2:1 to subcutaneous injections of Nplate (n=42 in splenectomized study and n=41 in non-splenectomized study) or placebo (n=21 in both studies). The primary endpoints assessed the efficacy of Nplate as measured by a durable platelet response and treatment safety. Durable response was defined as a platelet count above 50,000 per microliter during six or more of the last eight weeks of treatment without rescue therapy ever being administered.

-- Durable Platelet Response: The durable response rate was significantly greater in patients treated with Nplate compared to those in the placebo group in both studies (difference in proportion of splenectomized patients responding 38 percent (95 percent CI (23.4-52.8 percent); p less than 0.0001); difference in proportion of non-splenectomized patients responding 56 percent (95 percent CI (38.7-73.7 percent); p less than 0.0001)). In the placebo groups, no splenectomized patients and only one non-splenectomized patient achieved a durable platelet response.

-- Overall Platelet Response: The overall platelet response (either durable or transient response, with transient defined as greater than or equal to 4 weekly platelet responses from week two to 25) was 88 percent (36/41) in non-splenectomized patients compared to 14 percent (3/21) in the placebo group; and 79 percent (33/42) in splenectomized patients given Nplate compared to no splenectomized patients given placebo (p less than 0.0001).

-- Platelet Counts: Nplate-treated patients achieved platelet counts of 50,000 per microliter or more for an average of 13.8 weeks in the splenectomized group and 15.2 weeks in the non-splenectomized group compared with 0.2 and 1.3 weeks for patients in the respective placebo groups.

-- Reduction or Discontinuation of Concurrent Therapies: In both studies, 23 (12 splenectomized and 11 non-splenectomized) patients with Nplate and 16 (six splenectomized and 10 non-splenectomized) patients in the placebo group received concurrent ITP therapy with corticosteroids, azathioprine, and/or danazol. During the first 12 weeks of the study, 52 percent of the Nplate patients and 19 percent of the placebo patients discontinued all of their concurrent ITP treatments. An additional 35 percent of the Nplate patients and 19 percent of the placebo patients reduced at least one of their concurrent ITP medicines by more than 25 percent.

-- Rescue Medications: Significantly more patients in the placebo group received rescue treatment to increase platelet counts to prevent or treat bleeding compared to the Nplate-treated patients (57 percent placebo vs. 26 percent Nplate-treated splenectomized group; 62 percent placebo vs. 17 percent Nplate-treated non-splenectomized group) (p less than 0.0001). Rescue medication was defined as an increased dose of concurrent ITP drug, or the use of any new drug to increase platelet counts.

Adverse event rates were similar between the Nplate and placebo groups. According to the study authors, a study analysis indicated no difference in the safety profile between splenectomized and non-splenectomized ITP patients treated with Nplate, and therefore the authors pooled safety data for all patients in the Nplate and placebo groups.

In one splenectomized Nplate-treated patient, an increase in bone marrow reticulin that returned to baseline three months after withdrawal of Nplate was reported as a treatment-related serious adverse event. The other treatment-related serious adverse event reported was a peripheral thrombosis that was successfully treated, allowing study continuation. Deaths on-study included two patients in the placebo group and one in the Nplate group.

Significant bleeding events (rated as severe, life-threatening or fatal) were reported in 12 percent of patients in the placebo group compared to seven percent of Nplate patients. No patient tested positive for neutralizing antibodies against thrombopoietin.

The most common adverse events reported in patients treated with Nplate were headache, fatigue, epistaxis, arthralgia, and contusion.

Amgen filed for regulatory approval of Nplate for use in the treatment of thrombocytopenia in adults with chronic ITP in the United States (U.S.) and has received priority review from the U.S. Food and Drug Administration (FDA). Additionally, Amgen has submitted regulatory filings for the same indication in the European Union, Canada and Australia.

About Nplate

Romiplostim is an investigational thrombopoiesis-stimulating protein 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 binds to the TPO receptor, which activates the pathway necessary for growth and maturation of bone marrow megakaryocyte cells, resulting in increased platelet production. In 2004, the 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 also has received orphan designation for this proposed indication in 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 levels of platelets in the blood. Increasing the rate of platelet production may address low platelet levels 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 Jan. 31, 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 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.

SOURCE: Amgen Inc.

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