



FDA Approves Nplate(TM) for Long-Term Treatment of Adult Chronic ITP

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First and Only Approved Platelet Producer Represents New Treatment Approach for Serious Chronic Autoimmune Disorder

Amgen to Launch Nplate(TM) NEXUS Program to Provide Treatment Access and Patient Support Programs

THOUSAND OAKS, Calif., Aug 22, 2008 (BUSINESS WIRE) -- Amgen Inc. (NASDAQ: AMGN) today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved Nplate(TM) (romiplostim), the first and only platelet producer for the treatment of thrombocytopenia in splenectomized (spleen removed) and non-splenectomized adults with chronic immune thrombocytopenic purpura (ITP). Nplate, the first FDA-approved peptibody protein, works by raising and sustaining platelet counts, representing a novel approach for the long-term treatment of this chronic disease.

Chronic ITP is a serious autoimmune disorder characterized by low platelet counts in the blood (thrombocytopenia), which can lead to serious bleeding events. Recognized as an orphan disease, chronic ITP affects an estimated 60,000 adult patients in the U.S. and is considered an unmet need by the FDA.

"Until now, patients suffering from chronic ITP have had limited available treatment options, many of which are often unsuitable for long-term use due to side effects and tolerability issues," said David J. Kuter, M.D., Chief of Hematology, Massachusetts General Hospital, Boston. "Nplate represents the first long-term treatment for adult chronic ITP patients, providing a new treatment approach for this chronic disease."

The FDA approval of Nplate was based on efficacy and safety results from two pivotal Phase 3 studies of adult patients with chronic ITP, including both splenectomized and non-splenectomized patients. The overall response rate for Nplate was 83 percent (n=69/83, p less than 0.0001) of treated splenectomized and non-splenectomized patients, and platelet counts were raised and sustained in these six month studies. Additionally, patients treated with Nplate were able to reduce or discontinue their use of concomitant ITP medications and emergency medications (i.e., corticosteroids, IVIG, Win-Rho, Anti-D therapy).

Specifically, in the Phase 3 studies, non-splenectomized patients had an 88 percent (n=36/41, p less than 0.0001) overall platelet response and splenectomized patients had a 79 percent (n=33/42, p less than 0.0001) overall platelet response rate. Combined data from both trials shows clinically relevant bleeding events were significantly reduced by half in patients treated with Nplate compared to placebo (15 percent vs. 34 percent, p=0.018). Amgen continues to study the long-term efficacy and safety of Nplate for which there is more than three years of follow up safety and efficacy data.

"For those suffering from ITP, the daily fear of experiencing a serious bleeding episode can be emotionally stressful and extremely difficult for both patients and their families. We welcome the addition of new treatment options which offer new hope for the treatment of this serious disease," said Craig Conway, executive director of the Platelet Disorder Support Association.

In addition to improved clinical benefits, described in the FDA labeling, Amgen believes Nplate offers patients a positive net health benefit with fewer hospitalizations from bleeding events, as well as reduced need for emergency medications (IVIG and Win-Rho). Amgen expects the total costs of care for chronic ITP patients managed with Nplate to be less than or comparable to the total costs of care with standard treatment regimens.

Amgen also announced it will launch the Nplate(TM) NEXUS (Network of EXperts Understanding and Supporting Nplate(TM) and Patients) Program, a multi-faceted program designed to provide comprehensive access, support and education for chronic ITP patients, their caregivers and healthcare providers. The Nplate(TM) NEXUS Program is part of the Risk Evaluation and Mitigation Strategy (REMS) developed by Amgen in partnership with the FDA to assure safe use of Nplate while minimizing risk. The program will facilitate appropriate use of Nplate, provide patient support through education and resources and help with ongoing follow up through safety data collection.

Through the Nplate(TM) NEXUS Program, eligible patients who are uninsured, underinsured, or unable to afford their insurance co-payments may be able to receive reimbursement support and other assistance from Amgen. For example, one such program helps cover up to 50 percent of an eligible, commercially-insured patient's co-payments for Nplate. Recognizing that some patients may not have healthcare coverage, Amgen continues to offer another program for all of its innovative products, including Nplate, which provides product free of charge to eligible, low-income patients without insurance.

"Amgen is committed to advancing the discovery and development of new therapies for grievous illnesses where there is unmet medical need," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "The FDA approval of Nplate is the result of more than 15 years of research and represents an important biotechnology milestone as it is the first FDA-approved peptibody protein, an innovative platform for delivering targeted therapies."

Nplate was also approved for ITP by Australia's Therapeutic Goods Administration (TGA) in July 2008. Amgen has filed for regulatory approval of Nplate in the European Union (EU), Canada, and Switzerland and these applications are currently under review. Nplate has also received orphan designation for ITP in the EU (2005), Switzerland (2005) and Japan (2006).

More information about the Nplate(TM) NEXUS Program is available by calling 1-877-NPLATE1 (1-877-675-2831), or by visiting www.nplate.com.

About Adult ITP

Platelets are blood cells needed to prevent bleeding. 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.

There are limited approved treatments (i.e., corticosteroids, immunoglobulins) or surgical therapy (removal of the spleen) available to adult patients with chronic ITP. Currently, there are 140,000 treated chronic ITP patients in the U.S. and Europe. ITP affects about twice as many adult women as men.

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 Nplate

Nplate, Amgen's first peptibody protein, 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.

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 (eg, 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 50×10^9 to the ninth/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 Syndrome (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 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 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 Statements

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 August 22, 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, domestic and international trends toward managed care and health care 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.

SOURCE: Amgen Inc.

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