Nplate(TM) (Romiplostim) Receives Positive Opinion for Marketing Authorisation in the European Union

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

THOUSAND OAKS, Calif., Nov. 21 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) today announced that the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending marketing authorisation for Nplate(TM) (romiplostim) in the European Union (EU). The CHMP recommends Nplate for adult chronic immune (idiopathic) thrombocytopenia purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Nplate may be considered as second line treatment for adult non-splenectomised patients where surgery is contra-indicated.

"Nplate will address an unmet medical need for thousands of patients in the European Union as it is a unique treatment option that increases platelet production and avoids immune suppression in adult chronic ITP patients," said Willard Dere, M.D., senior vice president and international chief medical officer at Amgen.

The novel peptibody technology upon which romiplostim is based represents a promising new approach for treating adult patients with chronic ITP, an autoimmune disorder affecting an estimated 50,000 people in the EU, which can lead to serious bleeding events that can be potentially life threatening.

Nplate, a thrombopoietin (TPO) mimetic, is a novel engineered therapeutic fusion protein with attributes of both peptides and antibodies, but is distinct from each. Nplate works similarly to 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.

The CHMP positive opinion is based on data from two separate placebo-controlled Phase 3 studies, demonstrating that platelet counts were raised and sustained in 83 percent of patients for both splenectomised and non-splenectomised groups when treated with Nplate. Additionally, patients treated with Nplate were able to reduce or discontinue concomitant ITP and emergency medications which are often not well tolerated or whose effects are transient (i.e. corticosteroids, IVIG, Win-Rho Anti-D therapy).

Upon completion of the Phase 3 studies almost 90 percent of patients elected to subsequently enroll into the romiplostim long term extension study which demonstrated that, after three years, Nplate continued to effectively increase and sustain platelet counts. In this open label long term extension study some patients were treated for over 156 weeks and in the interim analysis the median treatment duration in this study is 65 weeks.

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 platelet destruction although recent data suggest that the body's natural platelet production processes in ITP 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.

Currently available treatments (i.e., corticosteroids, immunoglobulins) 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 U.S. ITP affects about twice as many adult women as men.

About Nplate

Nplate was granted approval for ITP by the regulatory bodies in Australia in July and the United States (U.S.) in August 2008. In addition to the European Union (EU), Amgen has filed for regulatory approval of Nplate in Canada and Switzerland and these applications are currently under review. Nplate has also received orphan designation for ITP in the U.S. (2003), the EU (2005), Switzerland (2005) and Japan (2006).

Nplate is the first treatment specifically developed for ITP. It is also being investigated for potential use in pediatric ITP, myelodysplastic syndrome (MDS) and chemotherapy-induced thrombocytopenia (CIT).

Important EU Nplate Safety Information

The most common side effects are headache, fatigue, arthralgia, myalgia, injection site bruising, injection site pain, oedema peripheral, dizziness, muscle spasms, nausea, contusion, diarrhea, bone marrow disorder, influenza like illness, insomnia and pruritus.

Reoccurrence of thrombocytopenia and bleeding after cessation of treatment and increased bone marrow reticulin have been associated with romiplostim treatment in the clinical trials. Thrombotic/thromboembolic complications, progression of existing haematopoietic malignancies or Myelodysplastic Syndromes (MDS), and effects on red and white blood cells are all potential risks associated with romiplostim treatment. As with all therapeutic proteins, patients may develop antibodies to the therapeutic protein.

Important U.S. Nplate Safety Information

Serious adverse reactions associated with Nplate in clinical studies were bone marrow reticulin deposition and worsening thrombocytopenia after Nplate discontinuation. Additional risks include bone marrow fibrosis, thrombotic/thromboembolic complications, lack or loss of response to Nplate, and hematological malignancies and progression of malignancy in patients with a pre-existing hematological malignancy or Myelodysplastic Syndrome (MDS). Nplate is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than chronic ITP.

In the U.S. Nplate is available only through a restricted distribution program called Nplate(TM) NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) Program.

In the placebo-controlled studies, headache was the most commonly reported adverse drug reaction.

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 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 June 15, 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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