New Study Shows Nplate(R) Significantly Reduces Splenectomy Rate and Treatment Failure in Patients With Chronic ITP

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BERLIN, June 7 /PRNewswire-FirstCall/ -- Amgen Inc. (Nasdaq: AMGN) today released the results of a new study comparing Nplate(R) (romiplostim) to the medical standard of care (SOC) in non-splenectomised adult patients with chronic immune thrombocytopenic purpura (ITP). Chronic ITP is a serious autoimmune disorder characterised by low platelet counts in the blood (thrombocytopenia), which can lead to serious bleeding events. The study results show Nplate significantly reduced the incidences of splenectomy and treatment failures in non-splenectomised adult patients with chronic ITP when compared to medical SOC. The results were presented today as an oral presentation at the 14th congress of the European Hematology Association (EHA abstract #1672).

"In this study, patients receiving Nplate experienced significant clinical efficacy benefits, including a reduction in bleeding events, compared to the standard of care," said Dr. Mathias Rummel, head of hematology at the Hospital of the Justus-Liebig University, Giessen, Germany. "Nplate is a unique treatment option that can help us better manage patients with chronic ITP. It addresses an unmet medical need for our patients as it increases platelet production and avoids immune suppression."

The study results show that only 8 percent of Nplate patients (13/157) underwent splenectomy or discontinued the study prior to reporting a splenectomy compared with 35 percent of patients (27/77) in the SOC group. Furthermore, 12 percent of Nplate patients (19/157) experienced treatment failure or discontinued the study compared with 27 percent of the SOC patients (21/77). Treatment failures were defined as patients having platelet counts less than or equal to 20,000 platelets per microliter for four consecutive weeks at the highest recommended dose and schedule, a major bleeding event, and/or a change in therapy due to intolerable side effects or bleeding symptoms. Patients who changed their therapy to splenectomy due to intolerable side-effects or bleeding symptoms were counted as both treatment failures and splenectomies.

A secondary analysis excluding patients who discontinued the study showed a similar trend in the reduction in splenectomy and treatment failure in the Nplate group compared to the SOC group. Only 1 percent of Nplate patients (2/157) underwent a splenectomy compared with 19 percent of SOC patients (15/77). Additionally, 5 percent of Nplate patients (8/157) experienced treatment failure compared to 12 percent of SOC patients (9/77).

The study also showed that the safety profile was comparable between the Nplate group and the group receiving the SOC. The safety analyses included all patients who received greater than or equal to 1 dose of Nplate or one type of SOC for ITP. Bleeding events with grade greater than or equal to 3 severity were reported by 8 percent of patients (6/75) in the SOC group, compared with 3 percent in the Nplate group (5/154).

About the Study

In total, 234 patients enrolled in this study, which assessed the efficacy and safety of Nplate compared to the medical SOC in adult patients with chronic ITP. SOC treatments were prescribed by the investigator according to standard institutional practices or therapeutic guidelines; the only treatments not allowed were investigational agents (rituximab was allowed) or other thrombopoietic agents.

Adverse events (AEs) were experienced by 92 percent of patients receiving the SOC (69/75) and by 95 percent of patients (146/154) receiving Nplate. The most common AEs in the SOC group were epistaxis (23 percent), nasopharyngitis (19 percent), and contusion (19 percent); in the Nplate group the most common AEs were headache (35 percent), fatigue (27 percent), and nasopharyngitis (23 percent). Treatment-related serious AEs were reported by 8 percent of SOC (6/75) and 5 percent of Nplate patients (7/154).

About Adult Chronic ITP

In patients with chronic ITP, platelets - or blood elements 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. The risk for serious bleeding events can increase when platelet counts drop to less than 30,000 platelets per microlitre; normal counts range from 150,000 to 400,000 platelets per microlitre. ITP has historically been considered a disease of platelet destruction although recent data suggest that the body's natural platelet production processes in chronic 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 (e.g., corticosteroids, immunoglobulins and others) 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 approximately 140,000 treated chronic ITP patients in Europe (EU) and the United States (U.S.). Chronic ITP affects about twice as many adult women as men.

About Nplate

In Europe, Nplate is indicated for the treatment of splenectomised adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Nplate may be considered as a second-line treatment for adult non-splenectomised ITP patients for whom surgery is contra-indicated.

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.

Nplate was the first platelet producer approved for chronic ITP by the regulatory bodies in Australia, the EU, Canada, and the U.S., and is under review in Switzerland. Nplate also has received orphan designation for chronic ITP in the U.S. (2003), the EU (2005), Switzerland (2005) and Japan (2006).

Nplate is the first treatment specifically developed for chronic ITP. It is also being investigated for potential use in paediatric ITP, myelodysplastic syndromes (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, peripheral oedema, dizziness, muscle spasms, nausea, contusion, diarrhoea, bone marrow disorder, influenza-like illness, insomnia and pruritus.

Recurrence 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.

For full prescribing information please see the Summary of Product Characteristics.

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, 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.

CBCs, including platelet counts and peripheral blood smears, should be monitored prior to initiation, throughout, and following discontinuation of Nplate therapy.

Nplate is available only through a restricted distribution program called Nplate(R) 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 7, 2009 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 modelled 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 labelling 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 labelling for the products, and not the information discussed in this news release.

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