



## Amgen Presents Data From First Nplate(R) Study in Children With Chronic ITP

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### Updated Five-Year Long-Term Data in Adults with Chronic ITP Also Presented at ASH Annual Meeting

NEW ORLEANS, Dec. 7 /PRNewswire-FirstCall/ -- Amgen Inc. (Nasdaq: AMGN) today announced results from its first Phase 1/2 study evaluating the safety and efficacy of Nplate® (romiplostim) in children with chronic immune thrombocytopenic purpura (ITP). Chronic ITP is a serious autoimmune disorder characterized by low platelet counts in the blood (thrombocytopenia), which can lead to serious bleeding events. The data were presented as an oral presentation at the 2009 American Society of Hematology (ASH) Annual Meeting and Exposition (ASH Abstract #680). Additionally, updated five-year follow-up results from an ongoing, open-label extension study in adults were presented and add to the data available on the long-term efficacy and safety of Nplate in adult patients with chronic ITP (ASH Abstract #681).

#### *Results from Phase 1/2 Study in Children (Abstract #680)*

ITP in children most commonly presents as an acute illness; however, 20-30 percent of these cases will persist as chronic ITP (duration over six months). Results of the study showed that treatment with Nplate appeared to be generally well-tolerated compared to placebo in children (aged 12 months to less than 18 years old) with chronic ITP (treatment related adverse events = 18 percent vs. 20 percent, respectively).

"Currently, most drug treatment options for children with chronic ITP involve immunosuppression," said Dr. George R. Buchanan, professor of Pediatrics at the University of Texas Southwestern Medical Center at Dallas. "This is the first study of an agent that stimulates platelet production in the pediatric population. The results suggest that Nplate could potentially be an important treatment option for selected children suffering from chronic ITP."

Safety results of the study showed that adverse event rates were similar between those patients treated with Nplate or placebo with most adverse events being mild to moderate in severity. Most frequent adverse events in patients taking Nplate or placebo were headache (35 percent vs. 40 percent, respectively), epistaxis (35 percent vs. 20 percent, respectively), cough (12 percent vs. 40 percent, respectively) and vomiting (12 percent vs. 40 percent, respectively).

Efficacy results showed that Nplate was effective in treating thrombocytopenia compared to placebo, with 88 percent of the 17 patients receiving Nplate achieving both efficacy endpoints during treatment (number of patients achieving a platelet count of over 50,000 platelets per microliter for two consecutive weeks during the treatment period and/or achieving an increase in the platelet count of 20,000 platelets per microliter above baseline for two consecutive weeks). Other observations included a decrease in rescue medication use, and numerically lower duration-adjusted bleeding adverse event rates with Nplate treatment as compared with placebo. None of the placebo-treated patients (n=5) achieved either efficacy endpoints.

#### *Study Design*

This Phase 1/2, 12-week treatment period evaluated the safety and efficacy of Nplate in the treatment of thrombocytopenia in children with chronic ITP (n=22). The study involved children with ITP aged 12 months to less than 18 years old with persistent severe thrombocytopenia for at least six months. The median age of study participants was 9.5 years. Nplate was administered subcutaneously at 1 mcg/kg once-weekly and doses were adjusted to a maximum dose of 10 mcg/kg weekly.

#### *Results from Ongoing, Long-Term Extension Efficacy and Safety Study (Abstract #681)*

Results from an ongoing, long-term extension study in adults that were also presented at the meeting showed that Nplate maintained platelet counts within a range of 50,000 to 200,000 platelets per microliter in the majority of adult patients with chronic ITP with minimal dose adjustments for up to nearly five years. Over the course of the study, a platelet count of greater than or equal to 50,000 platelets per microliter was achieved by 94 percent of 291 patients receiving Nplate, and the median platelet count remained greater than or equal to 50,000 platelets per microliter for the duration of the study after Week 1.

Patients were treated for a median of 48 weeks with a maximum duration of 244 weeks (n=4) and 33 percent of patients had previously undergone splenectomy.

"This updated five-year data represents the longest adult chronic ITP study ever conducted and the findings add to the data available on the long-term efficacy and safety of Nplate," said David J. Kuter, M.D., Chief of Hematology, Massachusetts General Hospital, Boston.

In addition, results showed that treatment with Nplate was generally well-tolerated and adverse event rates did not increase with longer duration of treatment. Of the 37 patients receiving concurrent ITP treatment (i.e., corticosteroids, IVIG, Win-Rho, Anti-D therapy), 78 percent were able to discontinue or reduce their dose of Nplate by more than 25 percent. Home administration of Nplate was achieved by 75 percent of patients.

#### *Study Design*

This is an ongoing, open-label, long-term efficacy and safety study of Nplate for the treatment of patients with chronic ITP. Nplate was administered once weekly by subcutaneous injection, with dose adjustments to maintain platelet counts in the target range (50,000 to 200,000 platelet count per microliter). The primary study objective was to determine long-term safety of Nplate. Secondary study objectives were to evaluate long-term platelet responses and the use of concurrent ITP therapies.

#### *About Adult ITP*

In patients with ITP, platelets - 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 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.

Other 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 approximately 90,000 adult chronic ITP patients in Europe and the United States (U.S.). ITP affects about twice as many adult women as men.

Nplate is only indicated to treat adult chronic ITP. Nplate is currently under investigation for children ages 12 months to 18 years old with persistent severe thrombocytopenia.

#### *About Nplate*

Nplate is the first platelet producer approved in the European Union (EU), Canada, Australia, Russia and the U.S. Nplate was granted approval for chronic ITP by the regulatory bodies in Australia, Canada, Europe, Russia and the U.S. 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 pediatric ITP, myelodysplastic syndromes (MDS) and chemotherapy-induced thrombocytopenia (CIT).

In the U.S., Nplate is indicated for the treatment of thrombocytopenia in patients with chronic immune 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.

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

Nplate was named as a recipient of the U.S. Prix Galien( )2009 "Best Biotechnology Product" award and also received the 2009 Scrip Awards for "Best New Drug."

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

Nplate is available only through a restricted distribution program called Nplate® 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.

#### *Important EU Nplate Safety Information*

The most common side effects are headache, fatigue, arthralgia, myalgia, injection site bruising, injection site pain, peripheral edema, 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 Nplate treatment in the clinical trials. Thrombotic/thromboembolic complications, progression of existing hematopoietic malignancies or MDS, and effects on red and white blood cells are all potential risks associated with Nplate treatment. 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](http://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 Dec. 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 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.

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