Amgen Presents Final Results from the Largest Phase 3 Open-Label Study Assessing the Safety and Efficacy of Nplate® (Romiplostim)

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Additional Key Nplate Data Also Presented at American Society of Hematology Annual Meeting

THOUSAND OAKS, Calif., Dec. 13, 2011 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that data from several key Nplate® (romiplostim) studies were presented at the 53rd Annual Meeting and Exposition of the American Society of Hematology (ASH), Dec. 10-13, 2011, in San Diego. Of note, final results from the international, Phase 3, open-label, single-arm '209 study evaluating the safety and efficacy of Nplate in adults with primary immune thrombocytopenia (ITP) demonstrated that Nplate induced a rapid platelet response in adult ITP patients with low platelet counts or bleeding symptoms and maintained a consistent safety profile (Abstract No. 3279).

In the study, incidence and type of adverse events (AEs) in patients treated with Nplate were consistent with those reported in previous studies. The most common side effects included headache, arthralgia and fatigue.

Approximately 90 percent of patients achieved each of the platelet response definitions, regardless of splenectomy status. Median time to response was one to two weeks. Over the course of the study, a doubling of the platelet count to greater than or equal to 50,000 platelets per microliter was achieved by 91 percent of patients who received Nplate. A platelet count increase of greater than or equal to 20,000 platelets per microliter from baseline was achieved by 93 percent of patients who received Nplate.

"We are very pleased to present the final results from the largest prospective study of Nplate in adult patients with primary ITP, which highlight Nplate's ability to successfully treat these patients," said Sean E. Harper, M.D., senior vice president of Global Development and chief medical officer at Amgen. "Additional data presented at the meeting in other disease states help further elucidate the safety and efficacy profile of Nplate. Collectively, these data help build upon our understanding of Nplate's treatment potential for patients with thrombocytopenia."

'209 Study Design
This was an open-label, single-arm study of Nplate for the treatment of adults with primary ITP. Nplate was administered once weekly, with dose adjustments to maintain platelet counts of greater than or equal to 50,000 platelets per microliter. The primary study objective was incidence of AEs and antibody formation. Secondary study objectives were to evaluate platelet responses defined as either (1) doubling of baseline count and a platelet count greater than or equal to 50,000 platelets per microliter or (2) a platelet count increase of greater than or equal to 20,000 platelets per microliter from baseline. Four hundred and seven patients were enrolled; median on-study treatment duration was 44 weeks. Fifty-one percent of patients had previously undergone splenectomy.

ADDITIONAL ABSTRACTS OF INTEREST INCLUDE:
Abstracts are available on the ASH website at http://www.hematology.org and updated data were presented at the meeting. All presentations will take place at the San Diego Convention Center unless noted otherwise.

Nplate ITP Data

- **Use of Rituximab in a Study Comparing the Thrombopoietin Mimetic Romiplostim with Standard of Care (SOC) in Patients with Immune Thrombocytopenia (ITP)** (Abstract No. 3282)
- **Sustained Hemostatic Platelet Counts in Adults With Immune Thrombocytopenia (ITP) Following Cessation of Treatment with the TPO Receptor Agonist Romiplostim: Report of 9 Cases** (Abstract No. 3281)
- **Clinical and Economic Outcomes Associated with Emergency Department Visits in Patients with Immune Thrombocytopenia** (Abstract No. 4209)
- **Hospitalizations in Pediatric Patients with Immune Thrombocytopenia** (Abstract No. 170)
- **Comparative Net Cost Impact of the Utilization of Romiplostim and Intravenous Immunoglobulin for the Treatment of Patients with Immune Thrombocytopenia in Quebec** (Abstract No. 4211)

Nplate MDS Data

- **Treatment with the Thrombopoietin (TPO)-Receptor Agonist Romiplostim in Thrombocytopenic Patients (Pts) with Low or Intermediate-1 (Int-1) Risk Myelodysplastic Syndrome (MDS): Results of a Randomized, Double-Blind, Placebo (PBO)-Controlled Study** (Abstract No. 117)
- **Update of an Open-Label Extension Study Evaluating the Long-Term Safety and Efficacy of Romiplostim in Thrombocytopenic Patients with Myelodysplastic Syndromes (MDS)** (Abstract No. 277)

Nplate CLL Data

- **c-Mpl is not expressed or functional at detectable levels on Primary Chronic lymphocytic leukemia (CLL) tumor samples** (Abstract No. 2849)

About Adult ITP
In patients with ITP, platelets – blood elements needed to prevent bleeding – are destroyed by the patient's own immune system. Recent data also suggest that low platelet counts in the blood may be caused by the inability of the body's natural processes to produce platelets. 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.

Some other available treatments (e.g., corticosteroids, immunoglobulins) are often unsuitable for long-term use due to tolerability issues and poor predictability of response. Surgical therapy (removal of the spleen) can be an option for many adult patients with chronic ITP, but does not work in all cases, and can be contraindicated in certain 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.

About Nplate
Nplate is approved in the U.S., European Union (EU), Canada, Australia, Russia, Mexico, Switzerland, Lichtenstein, Japan, Argentina, Israel, South Korea, Hong Kong, and Chile. Nplate also has received orphan designation for chronic ITP in the U.S. (2003), the EU (2005), Switzerland (2005), Japan (2006), Mexico (2010), South Korea (2010).

Nplate is the first FDA-approved treatment specifically for adult chronic ITP. It is also being investigated for potential use in children ages 12 months to 18 years old with persistent severe thrombocytopenia, and chemotherapy-induced thrombocytopenia (CIT).

In the U.S., Nplate is indicated for the treatment of thrombocytopenia in patients with chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than chronic ITP. Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase 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 contraindicated.

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." Nplate has also been honored with numerous awards throughout the EU, including a 2010 Prix Galien in France in the category of "Drugs for Rare Diseases," and the 2011 Prix Galien in Germany in the category of "Specialist Care." In September 2010, Nplate was awarded the 2010 International Prix Galien Award, an award granted every two years which recognizes the "best of the best" selected from previous national Prix Galien award recipients.

For more information about Nplate, please visit www.Nplate.com.

Important U.S. Nplate Safety Information
The risks associated with Nplate include progression of MDS to acute myelogenous leukemia (AML) in patients with MDS, thrombotic/thromboembolic complications, bone marrow reticulin formation and risk for bone marrow fibrosis, worsened thrombocytopenia after cessation of Nplate, and lack or loss of response to Nplate. 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 and myalgia.

The risks associated with Nplate include reoccurrence of thrombocytopenia, bleeding after cessation of treatment, increased bone marrow reticulin, thrombotic/thromboembolic complications, progression of existing MDS (in patients with MDS), loss of response to Nplate, and effects on red and white blood cells.

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 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, bone disease 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. Follow us on www.twitter.com/amgen.

Forward Looking Statements
This statement 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. 13, 2011 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 payers, 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.

CONTACT: Amgen, Thousand Oaks
Christine Regan, 805-447-5476 (Media)
Arvind Sood, 805-447-1060 (Investors)

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