Amgen and FDA Agree to Modify Nplate® (Romiplostim) Risk Evaluation and Mitigation Strategy

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Prescribing Physicians, Patients and Institutions no Longer Required to Enroll in Nplate® NEXUS Program

THOUSAND OAKS, Calif., Dec. 6, 2011 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the U.S. Food and Drug Administration (FDA) has modified the requirements of the Nplate® (romiplostim) Risk Evaluation and Mitigation Strategy (REMS) Program. Prescribing physicians, patients and institutions are no longer required to enroll in the safety monitoring program, called the Nplate® NEXUS (Network of EXperts Understanding and Supporting Nplate and Patients) Program, in order to prescribe or receive Nplate.

"The goals of the Nplate® NEXUS Program were to educate physicians and patients about treatment risks and benefits, and to define the long-term safety profile of Nplate," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "The FDA has now concluded that enrollment in a restricted distribution program is no longer necessary to prescribe or receive Nplate. Amgen will continue to monitor the safety profile of Nplate through clinical trials and post-marketing pharmacovigilance programs."

The primary modification of the REMS is the removal of the elements to assure safe use; however, a modified REMS communication plan will remain in place. In addition, the Medication Guide will no longer be part of the REMS, but will be part of approved product labeling.

From 2008 to 2011, the Nplate® NEXUS Program has collected long-term safety data from more than 5,200 patients. The restrictive elements of the REMS included enrollment of prescribers, patients and institutions to assist in collecting long-term safety information. Upon further review, the FDA and Amgen have determined that the safety information collected through the REMS, which is based on individual case safety reports, is inherently confounded by underlying medical conditions in the treated patient population and thus cannot be used to determine the precise role of Nplate in the development of the adverse events. Based in part on this determination, and the data submitted from clinical trials, the FDA and Amgen have concluded that the restricted elements of the REMS can be eliminated. For this reason enrollment of prescribers, patients and institutions and mandatory collection of safety data is no longer required.

As of Dec. 7, 2011, prescribing physicians and institutions will be able to order Nplate without enrolling themselves or patients in the Nplate® NEXUS Program. The program will continue to obtain information from already enrolled patients through Jan. 5, 2012, and Nplate® NEXUS Program support assistance will continue for 28 days after approval of the modified REMS.

About Adult ITP

In patients with immune thrombocytopenia (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 also 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, there are approximately 90,000 adult chronic ITP patients in Europe and the U.S. ITP affects about twice as many adult women as men.

The Nplate FIRST STEP™ Co-Pay Coupon Card Program

Last year, Amgen announced its co-pay coupon umbrella program, the Amgen FIRST STEP™ Program, for commercially insured patients. As part of that program, the Nplate FIRST STEP™ Co-Pay Coupon Card Program, is intended to provide assistance to eligible patients who need help meeting their Nplate deductible, co-insurance and/or co-payment (out-of-pocket) requirements. The Amgen FIRST STEP™ Program is significant among oncology commercial co-pay coupon programs, as it is the first program under the medical benefit with no income eligibility requirement. Under this program, eligible patients will incur no out of pocket costs for their first Nplate treatment associated with a new treatment regimen and will pay a maximum of $25 for subsequent injections. More information, eligibility requirements, restrictions and limitations about the co-pay coupon program are available at www.AmgenFIRSTSTEP.com.

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) and 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.

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. 6, 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.

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