Nplate(R) Data From MDS Studies Presented at ASH

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NEW ORLEANS, Dec. 6 /PRNewswire-FirstCall/ -- Amgen Inc. (Nasdaq: AMGN) today announced results from three studies on the safety and efficacy of Nplate® (romiplostim) in adult patients with myelodysplastic syndromes (MDS). MDS is a pre-leukemic condition in which early blood forming cells in the bone marrow are unable to mature normally, thereby limiting their ability to produce normal mature blood elements, which can lead to low platelet counts. The results of the studies were presented at the 2009 American Society of Hematology (ASH) Annual Meeting and Exposition (ASH Abstracts #1769, #1770 and #2765).

Interim Results from Long-Term Open-Label Extension Study of Nplate in MDS (Abstract #2765)

The ongoing, open-label extension study was designed to evaluate the safety and efficacy of Nplate in lower risk MDS patients. The primary endpoints of the interim study for presentation at ASH evaluated adverse event rates with long-term use of Nplate and incidence of antibody development to Nplate and/or thrombopoietin (TPO). Secondary endpoints evaluated the incidence of bleeding events and platelet response during the study period.

Nplate was generally well-tolerated, with the majority of patients (n=28) achieving a platelet response (61 percent) for eight or more consecutive weeks. The primary endpoint evaluating adverse event rates was met, with most patients experiencing adverse events that were mild to moderate with the most common being epistaxis (36 percent), arthralgia (29 percent), anemia (21 percent) and cough (21 percent). The co-primary endpoint was also met, as no neutralizing antibodies to Nplate or TPO were observed, nor progression to acute myeloid leukemia (AML). In addition, no cases of bone marrow fibrosis were reported.

Results for the secondary endpoint showed that 64 percent of patients (n=18) reported one or more bleeding events and 21 percent of patients (n=6) reported one or more clinically significant bleeding events. In the study, 29 percent of patients (n=8) received platelet transfusions. Frequency of bleeding events and platelet transfusions decreased over time. Bleeding events were evaluated on Common Terminology Criteria for Adverse Events (CTCAE) grades one to four, and clinically significant bleeding events were evaluated on CTCAE grades three and over, serious adverse events or any bleeding adverse event requiring intervention.

The data also showed that Nplate was effective with over half (54 percent) of patients (n=28) achieving a platelet response by week three and 61 percent achieving a durable platelet response overall (for eight or more consecutive weeks), meeting the additional secondary endpoint. Platelet response was defined as an absolute platelet increase of greater than or equal to 30,000 platelets per microliter for patients starting with less than 20,000 platelets per microliter, or an increase from less than 20,000 platelets per microliter to over 20,000 platelets per microliter and by at least 100 percent. The study showed that 82 percent of patients (n=28) had a platelet response and the median platelet response lasted 30 weeks.

"Both the safety and efficacy data are important given the limited treatment options available for those who suffer from low platelet counts due to MDS," said Dr. Hagop Kantarjian, Professor of Medicine and Chairman of the Department of Leukemia at The University of Texas M.D. Anderson Cancer Center.

Study Design

This long-term, follow-up, open-label global extension study included lower risk MDS patients who had completed a previous Nplate study and who had platelet counts of less than 50,000 platelets per microliter with no signs of disease progression. Patients received Nplate doses of 250 micrograms, 500 micrograms, 750 micrograms, or 1500 micrograms weekly or every two weeks based on previous dosing, with adjustments between 250 micrograms and 1000 micrograms.

Additional Phase 2 Nplate MDS Data (Abstract #1769 and #1770)

Data from two separate Phase 2 studies showed that patients with low and intermediate risk MDS currently receiving either decitabine or lenalidomide showed reduced incidence of clinically significant thrombocytopenic events and platelet transfusions with the addition of Nplate treatment.

In the study that examined patients with low and intermediate risk MDS receiving decitabine in combination with Nplate (Abstract #1769), the primary endpoint evaluated the incidence of clinically significant thrombocytopenic events as defined by platelet counts of less than 50,000 platelets per microliter by the third week of treatment, or receipt of platelet transfusions at any time during the study period.

The data showed that the primary endpoint was reached in 79 percent (n=14) of placebo patients and 80 percent (n=15) of Nplate patients and after the first cycle of treatment, median platelet counts at the beginning of each decitabine cycle were lower in placebo-treated patients than in Nplate-treated patients. In the last cycle, 30 percent of placebo treated patients (n=10) and 55 percent of Nplate treated patients (n=11) had reached median platelet count. In addition, results showed decreased platelet transfusions in Nplate-treated patients compared to placebo (47 percent vs. 57 percent, respectively).

Secondary endpoints were also met with results showing that treatment was generally well-tolerated in lower-risk MDS patients (all patients in the Nplate and placebo groups experienced at least one adverse event) with improved MDS treatment response after four cycles compared to placebo (47 percent vs. 36 percent, respectively) and decreased bleeding events (27 percent vs. 43 percent, respectively) in Nplate-treated patients compared to placebo. Adverse events were mild to moderate with similar treatment-related adverse events between patients taking Nplate and placebo (33 percent vs. 21 percent, respectively). Similar findings have been reported for use of Nplate in combination with azacytidine (vidaza).

The other study (Abstract #1770) examined patients with low and intermediate risk MDS receiving lenalidomide in combination with Nplate. The objective of the study was to evaluate the effect of Nplate on the incidence of clinically significant thrombocytopenic events and the overall safety and efficacy of Nplate in combination with lenalidomide. The data showed that treatment was generally well-tolerated with a comparable incidence of adverse events between all treatment groups with most frequent adverse events (appearing in greater than or equal to 10 percent of patients) in patients taking Nplate vs. placebo being diarrhea (38.5 percent vs. 45.5 percent, respectively), thrombocytopenia (16.3 percent vs. 36.4 percent), rash

(34.7 percent vs. 27.3 percent), edema peripheral (30.8 percent vs. 27.3 percent) and dizziness (11.6 percent vs. 27.3 percent). Data also showed increased platelet counts (31.5 percent vs. 17 percent) and reduced the need for platelet transfusions (19 percent vs. 25 percent) compared to placebo. Adverse events were mild to moderate with similar rates of adverse events between patients taking Nplate and placebo (100 percent vs. 91 percent).

Study Design

Both studies were multi-center, randomized, double-blind, placebo controlled studies that involved low and intermediate risk MDS patients receiving Nplate and decitabine (n=28) or lenalidomide (n=39). Patients received four 28-day cycles of decitabine or lenalidomide in addition to Nplate or placebo. At the end of treatment, there was an optional open-label extension period for patients taking the study drug and Nplate. MDS treatment response (complete response, partial response, stable disease, progressive disease or unknown) was determined by the investigator based on modified MDS Investigator Working Group (IWG) guidelines.

About Myelodysplastic Syndromes

MDS is a disorder in which the production of normal blood cells by the bone marrow is disrupted. There is no curative treatment for MDS, with the exception of bone marrow transplantation, and roughly 70 percent of all patients with MDS encounter complications or progression due to acute myeloid leukemia. MDS affects all ages, from children to adults, with the highest prevalence in those over sixty years of age.

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

About Nplate

Nplate was the first platelet producer approved in the European Union (EU), Canada, Australia, Russia and the United States (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, MDS and 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 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 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.

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. 6, 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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