



Amgen Highlights Data to be Presented at ASH

November 30, 2009

Nplate(R) Data Documents Long-Term Safety and Efficacy for Treatment of Serious Chronic Autoimmune Disorder

THOUSAND OAKS, Calif., Nov. 30 /PRNewswire-FirstCall/ -- Amgen Inc. (Nasdaq: AMGN) today announced that it will present updated long-term safety and efficacy data for Nplate® (romiplostim) in adult chronic immune (idiopathic) thrombocytopenic purpura (ITP). Additionally, Amgen will present the first Nplate study in a pediatric setting as well as in patients with myelodysplastic syndromes (MDS) at the 2009 American Society of Hematology (ASH) Annual Meeting and Exposition (Dec. 5 - 8, 2009).

"We are excited to present data on the safety and efficacy of Nplate in the pediatric setting for the first time," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "Similar to adults who have chronic ITP, children living with this disease have limited treatment options. We will also present data from a large global study of Nplate as a treatment for thrombocytopenia in patients with MDS."

SELECTED ABSTRACTS OF INTEREST

Abstracts are available and can be viewed on the ASH website at www.hematology.org. Identified below are selected abstracts of interest on Amgen research. Updated data will be presented at the meeting.

Nplate

Researchers will present five year follow-up results from the ongoing, open-label extension study on the long-term safety and efficacy of Nplate in adult patients with chronic ITP. Chronic ITP is a serious autoimmune disorder characterized by low platelet counts in the blood (thrombocytopenia), which can lead to serious bleeding events. These results support previously presented data which illustrated Nplate sustained platelet counts with extended treatment. Additionally, data regarding pediatric treatment of ITP will be presented, as well as results for Nplate in MDS.

- Abstract No. 681 (Embargoed until Dec. 7, 5:00pm): "Long-term Efficacy and Safety of Romiplostim for the Treatment of Patients with Chronic Immune Thrombocytopenia (ITP): 5-year Update from an Open-label Extension Study"
- Abstract No. 680 (Embargoed until Dec. 7, 4:45pm): "A Randomized, Double-Blind, Placebo-Controlled Phase 1/2 Study to Determine the Safety and Efficacy of Romiplostim in Children With Chronic Immune (Idiopathic) Thrombocytopenic Purpura (ITP)"

MDS Data

- Abstract No. 1769 (Embargoed until Dec. 5, 5:30pm): "Efficacy and Safety of Romiplostim in Patients with Low or Intermediate-Risk Myelodysplastic Syndrome (MDS) Receiving Decitabine"
- Abstract No. 1770 (Embargoed until Dec. 5, 5:30pm): "Randomized Phase II Study Evaluating the Efficacy and Safety of Romiplostim Treatment of Patients with Low or Intermediate Risk Myelodysplastic Syndrome (MDS) Receiving Lenalidomide"
- Abstract No. 2765 (Embargoed until Dec. 6, 6:00pm): "An Open-Label Extension Study Evaluating the Long-Term Safety and Efficacy of Romiplostim in Thrombocytopenic Patients (Pts) with Myelodysplastic Syndromes (MDS)"

Aranesp® (darbepoetin alfa)

Researchers will also present efficacy and safety data from an independent investigator-led study that is part of the Aranesp Pharmacovigilance program.

- Abstract No. 1701 (Embargoed until Dec. 5, 5:30pm): "Efficacy and Safety of Prophylactic Use of Darbepoetin Alfa in Patients with Diffuse Large B-Cell Lymphoma (DLBCL) Treated with Immunochemotherapy: Results of the Interim Analysis of the LNH03-6B GELA Study"

About Adult 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 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.

Currently 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.

About Nplate

Nplate was 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, MDS 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 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 the recipient of the U.S. Prix Galien 2009 "Best Biotechnology Product" award and also received the 2009 Scrip Award 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.

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, diarrhoea, 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 romiplostim 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 romiplostim treatment. As with all therapeutic proteins, patients may develop antibodies to the therapeutic protein.

About Aranesp

Aranesp was approved by the U.S. Food and Drug Administration (FDA) in September 2001 for the treatment of anemia associated with CRF for patients on dialysis and patients not on dialysis. In July 2002, the FDA approved weekly dosing of Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with nonmyeloid malignancies and in March 2006, the FDA approved every-three-week dosing in these patients.

Aranesp is a recombinant erythropoietic protein (a protein that stimulates production of red blood cells, which carry oxygen). Amgen revolutionized the treatment of anemia with the development of recombinant erythropoietin, Epoetin alfa. Building on this heritage, Amgen developed Aranesp, a unique erythropoiesis stimulating protein, which contains two additional sialic acid-containing carbohydrate chains compared to the epoetin alfa molecule and remains in the bloodstream longer than epoetin alfa as demonstrated by its longer half-life.

Aranesp was granted marketing authorization by the European Commission in 2001 for the treatment of anemia associated with chronic renal failure (CRF), also known as chronic kidney disease (CKD), in adults and pediatric subjects 11 years of age or older. In 2002, the European Commission approved Aranesp for the treatment of anemia in adult cancer patients receiving chemotherapy with solid tumors. This patient population was subsequently expanded in 2003 to include treatment of symptomatic anemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. Approval was granted in 2004 for extended dosing intervals of once-every-three-weeks in the treatment of anemia in adult cancer patients with non-myeloid malignancies who are receiving chemotherapy and up to once-per-month Aranesp administration in the treatment of anemia in CKD patients not on dialysis. In 2006, the Aranesp label was updated to allow CKD patients on dialysis to switch from rHuEPO one to three times a week to Aranesp every two weeks. In 2007, the Aranesp label was updated to allow for treatment of anemia associated with CRF, in all European pediatric patients on dialysis or not on dialysis.

Important Aranesp Safety Information

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR and THROMBOEMBOLIC EVENTS, and TUMOR PROGRESSION

Renal failure: Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Cancer:

- ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers when dosed to target a hemoglobin of greater than or equal to 12 g/dL.
- The risks of shortened survival and tumor progression have not been excluded when ESAs are dosed to target a hemoglobin of less than 12 g/dL.
- To minimize these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusions.
- Use only for treatment of anemia due to concomitant myelosuppressive chemotherapy.
- ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure. (This information is specific to the U.S. prescribing information)
- Discontinue following the completion of a chemotherapy course.

Aranesp is contraindicated in patients with uncontrolled hypertension.

All patients, including patients with cancer or chronic kidney failure:

- You may get serious heart problems such as heart attack, stroke, heart failure, and may die sooner if you are treated with Aranesp to a hemoglobin

level above 12 g/dL.

-- You may get blood clots at any time while taking Aranesp. If you are receiving Aranesp and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus).

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 Nov. 30, 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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