



Amgen Highlights Data to Be Presented at American Society of Hematology Annual Meeting

December 2, 2010

Final Results From The Largest And Longest Study Of Nplate(R) For The Treatment Of Adult Chronic ITP To Be Presented

Amgen Expands Amgen FIRST STEP(TM) Program Co-Pay Coupon Benefits To Help Patients With Out-of-Pocket Costs For Neulasta(R) And Nplate(R)

THOUSAND OAKS, Calif., Dec. 2, 2010 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced that it will present data from several key Nplate(R) (romiplostim) studies at the 52nd Annual Meeting and Exposition of the American Society of Hematology (ASH), Dec. 4-7, 2010, in Orlando, Fla. Results from six studies evaluating Nplate in adult patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) add to the growing body of data supporting the use of Nplate in this setting, including the final efficacy and safety results from the largest and longest study of Nplate in adult chronic ITP. Amgen will also present data for other marketed products including Neulasta(R) (pegfilgrastim) and Aranesp(R) (darbepoetin alfa).

"The complete results from a 5-year open-label extension study of Nplate in the adult chronic ITP setting show that Nplate increases and sustains platelet counts in these patients and that adverse event rates were consistent with those reported in previous studies," said Sean Harper, M.D., senior vice president, Global Development and Chief Medical Officer at Amgen. "This is the largest and longest study of Nplate in this setting, and reinforces the potential of Nplate as a long-term treatment option."

Amgen also announced the expansion of its Neulasta FIRST STEP(R) Program to its newly established co-pay coupon umbrella program, the Amgen FIRST STEP(TM) Program for commercially insured patients. The Amgen FIRST STEP(TM) Program will feature the Nplate FIRST STEP(TM) Program and Neulasta FIRST STEP(R) Programs. The Amgen FIRST STEP(TM) 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. The program is intended to help eligible patients meet their deductible, co-insurance, and/or co-payment requirements under the medical benefit for Neulasta and Nplate. Under this program, eligible patients will incur no out of pocket costs for their first Nplate or Neulasta 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 AmgenFIRSTSTEP.com.

SELECTED ABSTRACTS OF INTEREST INCLUDE:

Abstracts are available on the ASH website at <http://www.hematology.org> and updated data will be presented at the meeting.

Nplate ITP Data

- **Long-Term Efficacy and Safety of Romiplostim Treatment of Adult Patients with Chronic Immune Thrombocytopenia (ITP): Final Report from an Open-Label Extension Study**

(Abstract No. 68; Oral Presentation; Sunday, Dec. 5, 4:45 p.m. EST, room 230)

- **The Effects of Romiplostim or Standard of Care (SOC) on Splenectomy and Treatment Failure of Patients Who Had Immune Thrombocytopenia (ITP) for Less Than or Equal to One Year**

(Abstract No. 3702; Poster III-481; Monday, Dec. 6, 6:00 p.m.-8:00 p.m. EST, Hall A3/A4)

- **Analysis of Mortality Rates During Romiplostim Clinical Studies of Patients (Pts) with Immune Thrombocytopenia (ITP)**

Abstract No. 3701; Poster III-480; Monday, Dec. 6, 6:00 p.m.-8:00 p.m. EST, Hall A3/A4)

- **Patient Quality of Life (QoL) in Nonsplenectomized Immune Thrombocytopenia (ITP) Patients Receiving Romiplostim or Medical Standard of Care (SOC)**

(Abstract No. 569; Oral Presentation; Monday, Dec. 6, 3:45 p.m. EST, Room 340)

- **Evaluation of Romiplostim in a Randomized Placebo-Controlled Phase 3 Study of a Japanese Population with Chronic Immune Thrombocytopenia (ITP)**

(Abstract No. 3704; Poster III-483; Monday, Dec. 6, 6:00 p.m.-8:00 p.m. EST, Hall A3/A4)

- **Impact Assessment of Immunogenicity of Romiplostim in Subjects with Immune Thrombocytopenic Purpura (ITP)**

Abstract No. 2517; Poster II-397; Sunday, Dec. 5, 6:00 p.m.-8:00 p.m. EST, Hall A3/A4)

Nplate MDS Data

- **Update from an Open-Label Extension Study Evaluating the Long-Term Safety and Efficacy of Romiplostim in**

Thrombocytopenic Patients (Pts) with Myelodysplastic Syndromes (MDS)

(Abstract No. 1885; Poster I-865; Saturday, Dec. 4, 5:30 p.m.-7:30 p.m. EST, Hall A3/A4)

- **Associations Between Platelet Count and Survival and Disease Progression in Thrombocytopenic Patients with Myelodysplastic Syndromes**

Abstract No. 2905; Poster II-785; Sunday, Dec. 5, 6:00 p.m. EST, Hall A3/A4)

Neulasta

- **Pegfilgrastim Use Associated with Lower Risk of Hospitalization Than Filgrastim Use: A Retrospective US Claims Analysis**

(Abstract No. 3801; Poster III-580; Monday, Dec. 6, 6:00 PM-8:00 p.m. EST, Hall A3/A4)

- **Underreporting of Myelotoxicity with Emerging Regimens for Selected Hematologic Malignancies**

(Abstract No. 1501; Poster I-481; Saturday, Dec. 4, 5:30 p.m.-7:30 p.m. EST, Hall A3/A4)

- **Clinic Staff Time and Labor Costs Associated with Administering Pegfilgrastim as Compared with Filgrastim to Patients Receiving Myelosuppressive Chemotherapy: Results of a Health Economic Model**

(Abstract No. 1515; Poster I-495; Saturday, Dec. 4, 5:30 p.m.-7:30 p.m. EST, Hall A3/A4)

Aranesp

- **Real-Life Cost Analysis of Anemia Treatment with Erythropoiesis Stimulating Agents In Cancer Patients Receiving Chemotherapy**

(Abstract No. 3811; Poster III-590; Monday, Dec. 6, 6:00 p.m.-8:00 p.m. EST, Hall A3/A4)

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 the first platelet producer approved in the European Union (EU), Canada, Australia, Russia, Switzerland, Mexico and the U.S. Nplate also has received orphan designation for chronic ITP in the U.S. (2003), the EU (2005), Switzerland (2005), Japan (2006) and Mexico (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, 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 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." 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 <http://www.Nplate.com>.

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 U.S., Nplate is available only through a restricted distribution program called Nplate(R) 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, 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 Neulasta and NEUPOGEN(R)

Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

NEUPOGEN (filgrastim) is indicated to decrease the incidence of infection' as manifested by febrile neutropenia' in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Please refer to the Important European Product Safety Information section for approved indications in the EU.

Important U.S. Product Safety Information

Do not administer Neulasta or NEUPOGEN to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim. NEUPOGEN is contraindicated in patients with known hypersensitivity to E. coli-derived proteins, such as filgrastim.

Serious allergic reactions, including anaphylaxis, can occur in patients receiving Neulasta or NEUPOGEN. Permanently discontinue Neulasta or NEUPOGEN in patients with serious allergic reactions.

Splenic rupture, including fatal cases, can occur following the administration of Neulasta and NEUPOGEN.

Acute respiratory distress syndrome (ARDS) can occur in patients receiving Neulasta or NEUPOGEN.

Alveolar hemorrhage, manifesting as pulmonary infiltrates and hemoptysis requiring hospitalization, has been reported in healthy donors undergoing peripheral blood progenitor cell mobilization, an unapproved use of NEUPOGEN. Hemoptysis resolved with discontinuation of NEUPOGEN.

Bone pain and pain in extremity occurred at a higher incidence in Neulasta-treated patients as compared with placebo-treated patients. In clinical trials involving NEUPOGEN, bone pain was most frequently reported adverse event.

Important European Product Safety Information

For full prescribing information please see the Summary of Product Characteristics for each product.

NEUPOGEN is indicated for reduction in duration of neutropenia and incidence of febrile neutropenia after established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes); reduction in duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of NEUPOGEN are similar in adults and children receiving cytotoxic chemotherapy. NEUPOGEN is indicated for mobilisation of peripheral blood progenitor cells (PBPCs); long-term treatment to increase neutrophil counts and reduce incidence and duration of infection-related events in patients with severe congenital, cyclic, or idiopathic neutropenia treatment of persistent neutropenia in patients with advanced HIV infection.

NEUPOGEN is contraindicated in patients with hypersensitivity to filgrastim or excipients. Not to be used for escalation of cytotoxic chemotherapy doses above established regimens or administered to patients with severe congenital neutropenia (Kostman's Syndrome) with abnormal cytogenetics.

Administer NEUPOGEN with caution in secondary AML. Safety and efficacy of NEUPOGEN not established in *de novo* AML patients < 55 years with good cytogenetics (t(8;21), t(15;17) and inv(16)). The onset of pulmonary signs (cough, fever, dyspnoea) in association with radiological signs of pulmonary infiltrates and deterioration in pulmonary function may be preliminary signs of Acute Respiratory Distress Syndrome (ARDS). Discontinue NEUPOGEN and give appropriate treatment.

Other adverse events of special importance associated with NEUPOGEN include GvHD and fatalities in patients receiving G-CSF after allogeneic bone marrow transplantation, very rare cases of splenic rupture reported in healthy donors and patients, and hypersensitivity-type reactions in cancer patients. NEUPOGEN should be permanently discontinued in patients who experience a serious allergic reaction. NEUPOGEN is not recommended in period 24 hours before to 24 hours after chemotherapy. Neulasta is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Neulasta is contraindicated in patients with hypersensitivity to pegfilgrastim or excipients.

Neulasta should not be used in patients with MDS, CML and secondary AML. The safety and efficacy of Neulasta administration in *de novo* AML patients aged < 55 years with cytogenetics t(15;17) have not been established.

Neulasta should be discontinued following preliminary signs of ARDS. Spleen size should be carefully monitored and caution exercised when administering in patients with sickle cell disease. Safety and efficacy of Neulasta for mobilisation of blood progenitor cells in patients or healthy donors has not been adequately evaluated.

Other adverse events of special importance associated with Neulasta include bone pain, allergic-type reactions including anaphylaxis (pegfilgrastim should be permanently discontinued in patients who experience a serious allergic reaction) and very rare cases of splenic rupture including fatal cases. Neulasta should be administered approximately 24 hours after administration of cytotoxic chemotherapy.

About Aranesp

Aranesp was approved by the FDA in 2001 for the treatment of anemia associated with chronic renal failure (CRF) for patients on dialysis and patients not on dialysis. The European Commission granted marketing authorization for the same indication in 2001 and subsequently updated it for CRF patients with symptomatic anemia in 2008.

In 2002, the FDA approved Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with nonmyeloid malignancies.

The European Commission authorized the treatment of anemia caused by concomitantly administered chemotherapy in patients with non-haematological malignancies in 2002 and extended it to include non-myeloid malignancies in patients receiving chemotherapy in 2003.

Important U.S. Product Safety Information

Aranesp is indicated for the treatment of anemia due to the effect of concomitantly administered chemotherapy based on studies that have shown a reduction in the need for red blood cell transfusions in patients with metastatic, non-myeloid malignancies. Studies to determine whether Aranesp increases mortality or decreases progression-free/recurrence-free survival are ongoing.

- Aranesp is not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy.
- Aranesp is not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure due to the absence of studies that adequately characterize the impact of Aranesp on progression-free and overall survival.
- Aranesp use has not been demonstrated in controlled clinical trials to improve symptoms of anemia, quality of life, fatigue, or patient well-being.

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR EVENTS, THROMBOEMBOLIC EVENTS, STROKE AND INCREASED RISK OF TUMOR PROGRESSION OR RECURRENCE

Cancer:

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
- To decrease these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusion.
- Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense Aranesp, EPOGEN(R) or PROCRIT(R) to patients with cancer. To enroll in the ESA APPRISE Oncology Program, visit <http://www.esa-apprise.com/> or call 1-866-284-8089 for further assistance.
- Use ESAs 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.
- Discontinue following the completion of a chemotherapy course.
- ESAs are contraindicated in patients with uncontrolled hypertension.

Important European Product Safety Information

For full prescribing information please see the Summary of Product Characteristics.

Aranesp is indicated for treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.

Aranesp is contraindicated in patients with poorly controlled hypertension.

Controlled clinical trials have not shown significant benefits attributable to the administration of epoetins when haemoglobin concentration is increased beyond the level necessary to control symptoms of anaemia and to avoid blood transfusion.

In controlled clinical studies, use of Aranesp and other ESAs have shown:

- shortened time to tumour progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target Hb > 14 g/dL; ESAs are not indicated for use in this patient population
- shortened overall survival and increased deaths attributed to disease progression at 4 months in patients with metastatic breast cancer receiving chemotherapy when administered to target Hb 12-14 g/dL
- increased risk of death when administered to target Hb of 12 g/dl (7.5 mmol/l) in patients with active malignant disease receiving neither chemotherapy nor radiation therapy; ESAs are not indicated for use in this patient population.

In some clinical situations blood transfusion should be the preferred treatment for the management of anaemia in patients with cancer. The decision to

administer recombinant erythropoietins should be based on a benefit-risk assessment with the participation of the individual patient, which should take into account the specific clinical context. Factors that should be considered in this assessment should include the type of tumour and its stage; the degree of anaemia; life-expectancy; the environment in which the patient is being treated; and patient preference.

In patients with solid tumours or lymphoproliferative malignancies, if Hb >12 g/dL, the dose should be reduced/held to minimise the potential risk of thromboembolic events.

Discontinue use after the end of chemotherapy.

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 <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. 2, 2010 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 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
Megan Fox: +1 805-447-1423 (U.S. media, oncology)
Carrie Deverell: +41 41 3690 308 (European media)
Arvind Sood: +1 805-447-1060 (Investors)

(Logo: <http://photos.prnewswire.com/prnh/20081015/AMGENLOGO>)

SOURCE Amgen