Key Data For Amgen Medicines In Relapsed Multiple Myeloma And Acute Lymphoblastic Leukemia To Be Presented At ASH 2015

November 5, 2015

Data Underscore Company's Commitment to Difficult-to-Treat Blood Cancers
New Insights Further Strengthen Evidence of the Role of Kyprolis® (Carfilzomib) in Relapsed Multiple Myeloma
Growing Body of Clinical Evidence Validates Immunotherapy BLINCYTO® (Blinatumomab) for Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia

THOUSAND OAKS, Calif., Nov. 5, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that a number of important abstracts from the Company's oncology portfolio, including Kyprolis® (carfilzomib) for Injection, BLINCYTO® (blinatumomab), Nplate® (romiplostim) and Neulasta® (pegfilgrastim), are scheduled for presentation at the 57th American Society of Hematology (ASH) Annual Meeting and Exposition, Dec. 5–8, 2015, in Orlando, Fla.

"We look forward to sharing new data that further demonstrate our commitment to studying innovative cancer therapies across the treatment continuum for patients with difficult-to-treat conditions," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "In particular, we are encouraged by the breadth of data continuing to emerge from the Kyprolis clinical trial program, which further support the use of Kyprolis as an increasingly critical component in the treatment of patients with relapsed multiple myeloma."

Highlighted data in oral presentations and posters from the Kyprolis clinical trial program are based on subgroup analyses of the Phase 3 ENDEAVOR and ASPIRE studies evaluating Kyprolis-based regimens in more difficult-to-treat patients, including those at least 70 years of age, and those with a high-risk cytogenetic profile. The four oral presentations highlighting Kyprolis data are as follows:

- **Efficacy and Safety of Carfilzomib and Dexamethasone vs. Bortezomib and Dexamethasone with Relapsed Multiple Myeloma Based on Cytogenetic Risk Status: Subgroup Analysis from the Phase 3 Study ENDEAVOR (NCT01568866)**
  Abstract #30, Oral Presentation, Saturday, Dec. 5, at 8:45 a.m. ET in the Orange County Convention Center, Tangerine 2 (WF2)
- **Weekly Carfilzomib with Dexamethasone for Patients with Relapsed or Refractory Multiple Myeloma: Updated Results from the Phase 1/2 Study CHAMPION-1 (NCT01677858)**
  Abstract #373, Oral Presentation, Sunday, Dec. 6, at 4:30 p.m. ET in the Orange County Convention Center, Hall E1
- **Impact of Prior Treatment on Patients with Relapsed Multiple Myeloma Treated with Carfilzomib and Dexamethasone vs. Bortezomib and Dexamethasone in a Subgroup Analysis of the Phase 3 ENDEAVOR Study (NCT01568866)**
  Abstract #729, Oral Presentation, Monday, Dec. 7, at 3:15 p.m. ET in the Orange County Convention Center, Tangerine 2 (WF2)
- **Efficacy and Safety of Carfilzomib, Lenalidomide and Dexamethasone vs. Lenalidomide and Dexamethasone in Patients with Relapsed Multiple Myeloma Based on Cytogenetic Risk Status: Subgroup Analysis From the Phase 3 Study ASPIRE (NCT01080391)**
  Abstract #731, Oral Presentation, Monday, Dec. 7, at 3:45 p.m. ET in the Orange County Convention Center, Tangerine 2 (WF2)

The following three oral presentations on new data from our comprehensive acute lymphoblastic leukemia (ALL) development program for BLINCYTO will be presented:

- **Complete Molecular and Hematologic Response in Adult Patients with Relapsed/Refractory (R/R) Philadelphia Chromosome-positive B-precursor Acute Lymphoblastic Leukemia (ALL) following Treatment with Blinatumomab: Results from a Phase 2 Single-arm, Multicenter Study (ALCANTARA)**
  Abstract #679, Oral Presentation, Monday, Dec. 7, at 2:45 p.m. ET in the Orange County Convention Center, W224CDGH
- **Long-Term Outcomes after Blinatumomab Treatment: Follow-up of a Phase 2 Study in Patients (Pts) with Minimal Residual Disease (MRD) Positive B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)**
  Abstract #680, Oral Presentation, Monday, Dec. 7, at 3 p.m. ET in the Orange County Convention Center, W224CDGH
- **Treatment with anti-CD19 BiTE® Blinatumomab in Adult Patients with Relapsed/Refractory B precursor Acute Lymphoblastic Leukemia (r/r ALL) Post-Allogeneic Hematopoietic Stem Cell Transplantation**
  Abstract #861, Oral Presentation, Monday, Dec. 7, at 5 p.m. ET in the Orange County Convention Center, Tangerine 2 (WF2)

Key data from the Nplate clinical trial program will also be presented with new insights regarding use of Nplate in treating pediatric and adult immune thrombocytopenia patients, including:

- **A Phase 3, Randomized, Double-Blind, PBO-Controlled Study to Determine the Safety and Efficacy of Romiplostim**

in Children with Immune Thrombocytopenia (ITP)
Abstract #7, Oral Presentation, Saturday, Dec. 5, at 7:30 a.m. ET in Orange County Convention Center, W315

- **Effect of Romiplostim on Health Related Quality of Life in Children with Immune Thrombocytopenia and Associated Burden in Their Parents: Results from a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study**
  Abstract #37, Oral Presentation, Saturday, Dec.5, at 7:30 a.m. ET in Orange County Convention Center, W230
- **Rate of Bleeding-Rated Episodes (BREs) in Elderly Patients with Primary Immune Thrombocytopenia (ITP): A Population-Based Retrospective Cohort Study Using Medicare 20% Sample Data**
  Abstract #38, Oral Presentation, Saturday, Dec. 5, at 7:45 a.m. ET in Orange County Convention Center, W230
- **Safety and Efficacy of Long-Term Open-Label Dosing of Subcutaneous (SC) Romiplostim in Pediatric Patients With Immune Thrombocytopenia (ITP)**
  Abstract #3467, Poster, Monday, Dec. 7, from 6 p.m. ET in Orange County Convention Center, Hall A

Key data will be presented highlighting the risk of febrile neutropenia (FN) and the burden of oncology clinic visits for treatment with granulocyte-colony stimulating factor (G-CSF) therapy:

- **Annual Patient and Caregiver Burden of Oncology Clinic Visits for Granulocyte-Colony Stimulating Factor (G-CSF) Therapy in the United States (US)**
  Abstract #2066, Poster, Saturday, Dec. 5, at 5:30 p.m. ET in Orange County Convention Center, Hall A
- **Risk of Febrile Neutropenia (FN) in Select Myelosuppressive Chemotherapy Regimens**
  Abstract #3257, Poster, Sunday, Dec. 6, at 6 p.m. ET in Orange County Convention Center, Hall A

Four additional abstracts have been accepted for presentation highlighting investigational compounds from the Amgen pipeline, including:

- **Oprozomib, Pomalidomide, and Dexamethasone (OPomd) in Patients (Pts) With Relapsed and/or Refractory Multiple Myeloma (RRMM): Initial Results of a Phase 1b Study**
  Abstract #378, Oral Presentation, Sunday, Dec. 6, at 5:45 p.m. ET in the Orange County Convention Center, Hall E1
- **Expression of Novel Immune Checkpoint Molecules PVR and PVRL2 Confers a Negative Prognosis to Patients with Acute Myeloid Leukemia and Their Blockade Augments T-Cell Mediated Lysis of AML Cells Alone or in Combination with the BiTE® Antibody Construct AMG 330**
  Abstract #789, Oral Presentation, Monday, Dec. 7, at 5 p.m. ET in the Orange County Convention Center, W307
- **Identifying Immune Resistant Mechanisms to CD33/CD3 BiTE® Antibody Construct (AMG 330) Mediated Cytotoxicity**
  Abstract #3677, Poster, Monday, Dec. 7, from 6–8 p.m. ET in the Orange County Convention Center, Hall A

Amgen Webcast Investor Meeting

Amgen will host a webcast investor meeting at ASH on Monday, Dec. 7, 2015, at 7 p.m. ET. Sean E. Harper, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team and clinical investigators will participate to discuss data presented at ASH and Amgen's broader oncology portfolio of products.

Live audio of the conference call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found on Amgen's website, www.amgen.com, under *Investors*. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

About Amgen's Commitment to Oncology

Amgen Oncology is committed to helping patients take on some of the toughest cancers, such as those that have been resistant to drugs, those that progress rapidly through the body and those where limited treatment options exist. Amgen's supportive care treatments help patients combat certain side effects of strong chemotherapy, and our targeted medicines and immunotherapies focus on more than a dozen different malignancies, ranging from blood cancers to solid tumors. With decades of experience providing therapies for cancer patients, Amgen continues to grow its portfolio of innovative and biosimilar oncology medicines.

About Kyprolis® (carfilzomib) for Injection

Kyprolis® (carfilzomib) for Injection received approval from the U.S. Food and Drug Administration (FDA) in July 2015 for combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior lines of therapy.

Kyprolis is also indicated under FDA accelerated approval in July 2012 as a single agent for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending marketing authorization for Kyprolis in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma

who have received at least one prior therapy in September 2015.

Kyprolis is a product of Onyx Pharmaceuticals, Inc. Onyx Pharmaceuticals is a subsidiary of Amgen and holds development and commercialization rights to Kyprolis globally, excluding Japan. Kyprolis is also approved for use in Argentina, Israel, Kuwait, Mexico and Thailand. For more information about Kyprolis, visit www.kyprolis.com.

Important Safety Information Regarding Kyprolis® (carfilzomib) for Injection

Cardiac Toxicities

New onset or worsening of pre-existing cardiac failure (e.g., congestive heart failure, pulmonary edema, decreased ejection fraction), restrictive cardiomyopathy, myocardial ischemia, and myocardial infarction including fatalities have occurred following administration of Kyprolis. Death due to cardiac arrest has occurred within a day of Kyprolis administration.

Withhold Kyprolis for Grade 3 or 4 cardiac adverse events until recovery, and consider whether to restart Kyprolis based on a benefit/risk assessment.

Adequate hydration is required prior to each dose in Cycle 1. Monitor all patients for evidence of volume overload, especially patients at risk for cardiac failure. Adjust total fluid intake as clinically appropriate in patients with baseline cardiac failure or who are at risk for cardiac failure.

Patients ≥ 75 years, the risk of cardiac failure is increased. Patients with New York Heart Association Class III and IV heart failure, recent myocardial infarction, and conduction abnormalities may be at greater risk for cardiac complications.

Acute Renal Failure

Cases of acute renal failure and renal insufficiency adverse events (renal impairment, acute renal failure, renal failure) have occurred in patients receiving Kyprolis. Acute renal failure was reported more frequently in patients with advanced relapsed and refractory multiple myeloma who received Kyprolis monotherapy. This risk was greater in patients with a baseline reduced estimated creatinine clearance. Monitor renal function with regular measurement of the serum creatinine and/or estimated creatinine clearance. Reduce or withhold dose as appropriate.

Tumor Lysis Syndrome

Cases of Tumor Lysis Syndrome (TLS), including fatal outcomes, have occurred in patients receiving Kyprolis. Patients with multiple myeloma and a high tumor burden should be considered at greater risk for TLS. Adequate hydration is required prior to each dose in Cycle 1, and in subsequent cycles as needed. Consider uric acid lowering drugs in patients at risk for TLS. Monitor for evidence of TLS during treatment and manage promptly. Withhold Kyprolis until TLS is resolved.

Pulmonary Toxicity

Acute Respiratory Distress Syndrome (ARDS), acute respiratory failure, and acute diffuse infiltrative pulmonary disease such as pneumonitis and interstitial lung disease have occurred in patients receiving Kyprolis. Some events have been fatal. In the event of drug-induced pulmonary toxicity, discontinue Kyprolis.

Pulmonary Hypertension

Pulmonary arterial hypertension (PAH) was reported in patients treated with Kyprolis. Evaluate with cardiac imaging and/or other tests as indicated. Withhold Kyprolis for PAH until resolved or returned to baseline and consider whether to restart Kyprolis based on a benefit/risk assessment.

Dyspnea

Dyspnea was reported in patients treated with Kyprolis. Evaluate dyspnea to exclude cardiopulmonary conditions including cardiac failure and pulmonary syndromes. Stop Kyprolis for Grade 3 or 4 dyspnea until resolved or returned to baseline. Consider whether to restart Kyprolis based on a benefit/risk assessment.

Hypertension

Hypertension, including hypertensive crisis and hypertensive emergency, has been observed with Kyprolis. Some of these events have been fatal. Monitor blood pressure regularly in all patients. If hypertension cannot be adequately controlled, withhold Kyprolis and evaluate. Consider whether to restart Kyprolis based on a benefit/risk assessment.

Venous Thrombosis

Venous thromboembolic events (including deep venous thrombosis and pulmonary embolism) have been observed with Kyprolis. Thromboprophylaxis is recommended and should be based on an assessment of the patient's underlying risks, treatment regimen, and clinical status.

Infusion Reactions

Infusion reactions, including life-threatening reactions, have occurred in patients receiving Kyprolis. Symptoms include fever, chills, arthralgia, myalgia, facial flushing, facial edema, vomiting, weakness, shortness of breath, hypotension, syncope, chest tightness, or angina. These reactions can occur immediately following or up to 24 hours after administration of Kyprolis. Premedicate with dexamethasone to reduce the incidence and severity of infusion reactions. Inform patients of the risk and of symptoms of an infusion reaction and to contact a physician immediately if they occur.

Thrombocytopenia

Kyprolis causes thrombocytopenia with recovery to baseline platelet count usually by the start of the next cycle. Thrombocytopenia was reported in patients receiving Kyprolis. Monitor platelet counts frequently during treatment with Kyprolis. Reduce or withhold dose as appropriate.

Hepatic Toxicity and Hepatic Failure

Cases of hepatic failure, including fatal cases, have been reported during treatment with Kyprolis. Kyprolis can cause increased serum transaminases. Monitor liver enzymes regularly. Reduce or withhold dose as appropriate.

Thrombotic Thrombocytopenic Purpura /Hemolytic Uremic Syndrome (TTP/HUS)

Cases of TTP/HUS including fatal outcome have occurred in patients receiving Kyprolis. Monitor for signs and symptoms of TTP/HUS. Discontinue Kyprolis if diagnosis is suspected. If the diagnosis of TTP/HUS is excluded, Kyprolis may be restarted. The safety of reinitiating Kyprolis therapy in patients previously experiencing TTP/HUS is not known.

Posterior Reversible Encephalopathy Syndrome (PRES)

Cases of PRES have occurred in patients receiving Kyprolis. PRES was formerly known as Reversible Posterior Leukoencephalopathy Syndrome. Consider a neuro-radiological imaging (MRI) for onset of visual or neurological symptoms. Discontinue Kyprolis if PRES is suspected and evaluate. The safety of reinitiating Kyprolis therapy in patients previously experiencing PRES is not known.

Embryo-fetal Toxicity

Kyprolis can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals.

Females of reproductive potential should be advised to avoid becoming pregnant while being treated with Kyprolis and the potential hazard to the fetus if Kyprolis is used during pregnancy.

ADVERSE REACTIONS

The most common adverse events occurring in at least 20% of patients treated with Kyprolis in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, decreased platelets, dyspnea, diarrhea, decreased lymphocyte, headache, decreased hemoglobin, cough, edema peripheral.

The most common adverse events occurring in at least 20% of patients treated with Kyprolis in the combination therapy trial: decreased lymphocytes, decreased absolute neutrophil count, decreased phosphorus, anemia, neutropenia, decreased total white blood cell count, decreased platelets, diarrhea, fatigue, thrombocytopenia, pyrexia, muscle spasm, cough, upper respiratory tract infection, decreased hemoglobin, hypokalemia.

Full prescribing information is available at www.kyprolis.com.

About BLINCYTO® (blinatumomab)

BLINCYTO is a bispecific CD19-directed CD3 T cell engager that binds specifically to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T cells.

Bispecific T cell engager (BiTE®) antibody constructs are a type of immunotherapy being investigated for fighting cancer by helping the body's immune system to detect and target benign and malignant cells expressing a particular antigen. The modified antibodies are designed to engage two different targets simultaneously, thereby juxtaposing T cells (a type of white blood cell capable of killing other cells perceived as threats) to cancer cells. BiTE® antibody constructs help place the T cells within reach of the targeted cell, with the intent of allowing T cells to inject toxins and trigger the cell to die (apoptosis). BiTE® antibody constructs are currently being investigated for their potential to treat a wide variety of cancers.

BLINCYTO was granted breakthrough therapy status and priority review designations by the FDA, and is now approved in the U.S. for the treatment of Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor ALL. This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending marketing authorization for BLINCYTO for the treatment of adults with Ph- relapsed or refractory B-precursor ALL in September 2015.

Important U.S. Product Information Regarding BLINCYTO (blinatumomab)

BLINCYTO is indicated for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES

- **Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO. Interrupt or discontinue BLINCYTO® as recommended.**
- **Neurological toxicities, which may be severe, life-threatening or fatal, occurred in patients receiving BLINCYTO. Interrupt or discontinue BLINCYTO® as recommended.**

Contraindications

BLINCYTO is contraindicated in patients with a known hypersensitivity to blinatumomab or to any component of the product formulation.

Warnings and Precautions

- Cytokine Release Syndrome (CRS): Life-threatening or fatal CRS occurred in patients receiving BLINCYTO. Infusion

reactions have occurred and may be clinically indistinguishable from manifestations of CRS. Closely monitor patients for signs and symptoms of serious events such as pyrexia, headache, nausea, asthenia, hypotension, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased total bilirubin (TBILI), disseminated intravascular coagulation (DIC), capillary leak syndrome (CLS), and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS). Interrupt or discontinue BLINCYTO as outlined in the Prescribing Information (PI).

- Neurological Toxicities: Approximately 50% of patients receiving BLINCYTO® in clinical trials experienced neurological toxicities. Severe, life-threatening, or fatal neurological toxicities occurred in approximately 15% of patients, including encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. The median time to onset of any neurological toxicity was 7 days. Monitor patients for signs or symptoms and interrupt or discontinue BLINCYTO as outlined in the PI.
- Infections: Approximately 25% of patients receiving BLINCYTO® experienced serious infections, some of which were life-threatening or fatal. Administer prophylactic antibiotics and employ surveillance testing as appropriate during treatment. Monitor patients for signs or symptoms of infection and treat appropriately, including interruption or discontinuation of BLINCYTO as needed.
- Tumor Lysis Syndrome (TLS): Life-threatening or fatal TLS has been observed. Preventive measures, including pretreatment nontoxic cytoreduction and on treatment hydration, should be used during BLINCYTO treatment. Monitor patients for signs and symptoms of TLS and interrupt or discontinue BLINCYTO as needed to manage these events.
- Neutropenia and Febrile Neutropenia, including life-threatening cases, have been observed. Monitor appropriate laboratory parameters during BLINCYTO® infusion and interrupt BLINCYTO if prolonged neutropenia occurs.
- Effects on Ability to Drive and Use Machines: Due to the possibility of neurological events, including seizures, patients receiving BLINCYTO are at risk for loss of consciousness, and should be advised against driving and engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery while BLINCYTO is being administered.
- Elevated Liver Enzymes: Transient elevations in liver enzymes are associated with BLINCYTO treatment. The majority of these events were observed in the setting of CRS. The median time to onset was 15 days. Grade 3 or greater elevations in liver enzymes occurred in 6% of patients outside the setting of CRS and resulted in treatment discontinuation in less than 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase (GGT), and TBILI prior to the start of and during BLINCYTO® treatment. BLINCYTO treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if TBILI rises to > 3 times ULN.
- Leukoencephalopathy: Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO, especially in patients previously treated with cranial irradiation and anti-leukemic chemotherapy.
- Preparation and administration errors have occurred. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).

Adverse Events

- The most commonly reported adverse reactions (≥ 20%) in clinical trials were pyrexia (62%), headache (36%), peripheral edema (26%), febrile neutropenia (26%), nausea (25%), hypokalemia (23%), rash (21%), tremor (20%) and constipation (20%).
- Serious adverse reactions were reported in 65% of patients. The most common serious adverse reactions (≥ 2%) included febrile neutropenia, pyrexia, pneumonia, sepsis, neutropenia, device-related infection, tremor, encephalopathy, infection, overdose, confusion, *Staphylococcal* bacteremia, and headache.

Dosage and Administration Guidelines

- BLINCYTO is administered as a continuous intravenous infusion at a constant flow rate using an infusion pump which should be programmable, lockable, non-elastomeric, and have an alarm.
- It is very important that the instructions for preparation (including admixing) and administration provided in the full Prescribing Information are strictly followed to minimize medication errors (including underdose and overdose).

Please see full Prescribing Information and medication guide for BLINCYTO at www.BLINCYTO.com

About Nplate® (romiplostim)

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 immune 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. Safety Information Regarding Nplate (romiplostim)

Risk of Progression of Myelodysplastic Syndromes to Acute Myelogenous Leukemia

- In Nplate clinical trials of patients with myelodysplastic syndromes (MDS) and severe thrombocytopenia, progression from MDS to acute myelogenous leukemia (AML) has been observed.
- Nplate is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than chronic ITP.

Thrombotic/Thromboembolic Complications

- Thrombotic/thromboembolic complications may result from increases in platelet counts with Nplate use. Portal vein thrombosis has been reported in patients with chronic liver disease receiving Nplate.
- To minimize the risk for thrombotic/thromboembolic complications, do not use Nplate in an attempt to normalize platelet counts. Follow the dose adjustment guidelines to achieve and maintain a platelet count of ≥ 50 x 109/L.

Loss of Response to Nplate

- Hyporesponsiveness or failure to maintain a platelet response with Nplate should prompt a search for causative factors, including neutralizing antibodies to Nplate.
- To detect antibody formation, submit blood samples to Amgen (1-800-772-6436). Amgen will assay these samples for antibodies to Nplate and thrombopoietin (TPO).
- Discontinue Nplate if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the highest weekly dose of 10 mcg/kg.

Laboratory Monitoring

- Obtain CBCs, including platelet counts, weekly during the dose adjustment phase of Nplate therapy and then monthly following establishment of a stable Nplate dose.
- Obtain CBCs, including platelet counts, weekly for at least two weeks following discontinuation of Nplate.

Adverse Reactions

- In the placebo-controlled trials, headache was the most commonly reported adverse drug reaction, occurring in 35% of patients receiving Nplate and 32% of patients receiving placebo. Headaches were usually of mild or moderate severity.
- Most common adverse reactions (≥ 5% higher patient incidence in Nplate versus placebo) were Arthralgia (26%, 20%), Dizziness (17%, 0%), Insomnia (16%, 7%), Myalgia (14%, 2%), Pain in Extremity (13%, 5%), Abdominal Pain (11%, 0%), Shoulder Pain (8%, 0%), Dyspepsia (7%, 0%), and Paresthesia (6%, 0%).
- Nplate administration may increase the risk for development or progression of reticulin fiber formation within the bone marrow. This formation may improve upon discontinuation of Nplate. In a clinical trial, one patient with ITP and hemolytic anemia developed marrow fibrosis with collagen during Nplate therapy.

Please see full Prescribing Information for Nplate at www.Nplate.com.

About Neulasta® (pegfilgrastim)

Neulasta (pegfilgrastim) 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.

In a pivotal clinical trial, in patients with nonmyeloid malignancies undergoing myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia, treatment with Neulasta was shown to significantly reduce the incidence of febrile neutropenia as well as hospitalizations related to febrile neutropenia and the use of IV antibiotics.

Neulasta is administered by manual injection and is also available via the Neulasta Onpro™ kit, which was approved by the FDA in 2014 and includes a specially designed, single-use prefilled syringe co-packaged with an On-body Injector for Neulasta.

For more information about Neulasta, visit www.Neulasta.com and www.NeulastaHCP.com.

Important Safety Information Regarding Neulasta

Contraindication

Do not administer Neulasta to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.

Splenic Rupture

Splenic rupture, including fatal cases, can occur following the administration of Neulasta. Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving Neulasta.

Acute Respiratory Distress Syndrome

Acute respiratory distress syndrome (ARDS) can occur in patients receiving Neulasta. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Neulasta for ARDS. Discontinue Neulasta in patients with ARDS.

Serious Allergic Reactions

Serious allergic reactions, including anaphylaxis, can occur in patients receiving Neulasta. The majority of reported events occurred upon initial exposure. Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue Neulasta in patients with serious allergic reactions.

Allergies to Acrylics

The On-body Injector for Neulasta uses acrylic adhesive. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction.

Use in Patients with Sickle Cell Disorders

Severe sickle cell crises can occur in patients with sickle cell disorders receiving Neulasta. Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving filgrastim, the parent compound of pegfilgrastim.

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte colony-stimulating factor (G-CSF) receptor, through which pegfilgrastim and filgrastim act, has been found on tumor cell lines. The possibility that pegfilgrastim acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim is not approved, cannot be excluded.

The most common adverse reactions (≥ 5% difference in incidence) in placebo-controlled clinical trials are bone pain and pain in extremity.

Please see additional Neulasta Safety Information, by visiting www.amgen.com/medpro/products.html.

Please see the Neulasta Full Prescribing Information by clicking here

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen, we or us) 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 Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to Amgen's business. Unless otherwise noted, Amgen is providing this information as of Nov. 5, 2015, 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 and our partners 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 product liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. 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 (including products of our wholly-owned subsidiaries) 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 and our partners routinely obtain patents for our and their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' 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. Our efforts to integrate the operations of companies we have acquired may not be successful. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our ongoing restructuring plans. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase common stock.

The scientific information discussed in this news release relating to new indications for Amgen's products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration 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.

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