Amgen To Advance Understanding Of The Treatment Of Blood Cancers At 20th Congress of European Hematology Association (EHA)

May 27, 2015

THOUSAND OAKS, Calif., May 27, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present data from multiple Kyprolis® (carfilzomib) for Injection, BLINCYTO® (blinatumomab), oprozomib and Nplate® (romiplostim) studies at the 20th Congress of the European Hematology Association (EHA) taking place in Vienna, June 11 - 14, 2015. The data reinforce Amgen's commitment to advancing the care of patients with hematologic malignancies through the development of novel treatment approaches and continued evaluation of marketed products.

"We focus on blood cancers that have high unmet medical need, such as multiple myeloma and acute lymphoblastic leukemia, to make a positive impact for patients who desperately need more options," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The data being presented at EHA show advancements in understanding how novel treatment approaches, such as Kyprolis, BLINCYTO and oprozomib, can work across various patient populations and stages of the treatment continuum."

Key data include findings from clinical trials in multiple myeloma, acute lymphoblastic leukemia (ALL), Waldenström macroglobulinemia and immune thrombocytopenia (ITP). Notable abstracts and satellite symposia of interest include:

Kyprolis
In multiple myeloma, full results will be presented as a late-breaking oral presentation from the Phase 3 head-to-head ENDEAVOR trial evaluating Kyprolis and dexamethasone compared to Velcade® (bortezomib) and dexamethasone, as well as results from the Phase 1/2 CHAMPION-1 study and a secondary analysis from the pivotal Phase 3 ASPIRE study.

- **Carfilzomib and dexamethasone improves progression-free survival and response rates vs. bortezomib and dexamethasone in patients with relapsed multiple myeloma: the Phase 3 study ENDEAVOR**
  Abstract No. LB2071, Late-breaking Oral Presentation, Session Title: Late-breaking Abstracts 2, Sunday, June 14, Presentation Time: noon - 12:15 p.m. Central European Time (CET), Room A7
- **Effect of carfilzomib, lenalidomide, and dexamethasone vs. lenalidomide and dexamethasone in patients with relapsed multiple myeloma by line of therapy: interim results from the Phase 3 ASPIRE study**
  Abstract No. S427, Oral Presentation, Session Title: Multiple Myeloma - Clinical Studies 2, Saturday, June 13, Presentation Time: 11:45 a.m. - noon CET, Room A2+3
- **Weekly carfilzomib with dexamethasone for patients with relapsed or refractory multiple myeloma: updated results from the Phase 1/2 study CHAMPION-1 (NCT01677858)**
  Abstract No. P269, Poster Presentation, Session Title: Multiple Myeloma - Clinical 1, Friday, June 12, 5:15 p.m. - 6:45 p.m. CET, Poster Area (Hall C)
- **Impact of carfilzomib on health-related quality of life: results from a Phase 2 post-hoc analysis of single-agent carfilzomib in patients with relapsed and refractory multiple myeloma**
  Abstract No. E1433, e-Poster Presentation
- **Satellite Symposium: Charting new depths in the treatment of multiple myeloma**
  Thursday, June 11, 4:15 p.m. - 6:15 p.m. CET, Room C2, Messe Wien Vienna

BLINCYTO® (blinatumomab)
Blinatumomab data at EHA will focus on targeted patient populations within relapsed/refractory ALL to better understand response to treatment.

- **Blinatumomab safety and activity in older patients with relapsed/refractory B-precursor acute lymphoblastic leukemia in two Phase 2 studies**
  Abstract No. S115, Oral Presentation, Session Title: ALL Clinical Trials, Friday, June 12, Presentation Time: 12:30 p.m. - 12:45 p.m. CET, Room C1
- **Retreatment with blinatumomab after CD-19-positive relapse: experience from three trials in patients with relapsed/refractory B-precursor acute lymphoblastic leukemia**
  Abstract No. P165, Poster Presentation, Session Title: Acute Lymphoblastic Leukemia - Clinical 1, Friday, June 12, 5:15 p.m. - 6:45 p.m. CET, Poster Area (Hall C)
- **Influence of baseline factors on outcomes in patients with relapsed/refractory B-precursor acute lymphoblastic leukemia treated with blinatumomab**
  Abstract No. P161, Poster Presentation, Session Title: Acute Lymphoblastic Leukemia - Clinical 1, Friday, June 12, 5:15 p.m. - 6:45 p.m. CET, Poster Area (Hall C)
- **Satellite Symposium: T-cell engagement strategies for ALL: examining the emerging data**
  Thursday, June 11, 1:30 p.m. - 3:30 p.m. CET, Room Lehar 1 & 2, Reed Messe Vienna

Oprozomib
Updated results will be featured from three dose escalation studies of oprozomib, a novel oral proteasome inhibitor; one in combination with dexamethasone in patients with relapsed and/or refractory multiple myeloma, and two as a single agent in patients with hematologic malignancies,

including multiple myeloma and Waldenström macroglobulinemia, respectively.

- **Oprozomib and dexamethasone in patients with relapsed and/or refractory multiple myeloma: updated results from dose escalation in a Phase 1b/2, multicenter, open-label study**
  Abstract No. P653, Poster Presentation, Session Title: Multiple Myeloma - Clinical 3, Saturday, June 13, 5:15 p.m. - 6:45 p.m. CET, Poster Area (Hall C)
- **Updated results from a multicenter, open-label, dose escalation Phase 1b/2 study of single-agent oprozomib in patients with hematologic malignancies, including multiple myeloma**
  Abstract No. P646, Poster Presentation, Session Title: Multiple Myeloma - Clinical 3, Saturday, June 13, 5:15 p.m. - 6:45 p.m. CET, Poster Area (Hall C)
- **Updated results from a multicenter, open-label, dose escalation Phase 1b/2 study of single-agent oprozomib in patients with hematologic malignancies, including Waldenström macroglobulinemia**
  Abstract No. E1154, e-Poster Presentation

Nplate
Interim results from the PLATON trial, an observational clinical practice study of Nplate in patients with ITP, will be presented, focusing on the effect of Nplate on platelet counts in ITP patients in clinical practice, as well as the tolerability of Nplate.

- **An observational clinical practice study of romiplostim in patients with chronic immune thrombocytopenic purpura – PLATON interim results**
  Abstract No. E1415, e-Poster Presentation

Disease State Research
Amgen will also present a study at EHA that focuses on trends in splenectomy in adult patients with chronic ITP.

- **Recent time trends in the uptake of splenectomy in adults diagnosed with chronic immune thrombocytopenia: A nationwide historical cohort study in Denmark, 1996 - 2012**
  Abstract No. E1411, e-Poster Presentation

About Kyprolis® (carfilzomib) for Injection
On July 20, 2012, the U.S. FDA granted accelerated approval of Kyprolis for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent (IMiD) and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval was based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified. Kyprolis is under regulatory review by the European Medicines Agency (EMA).

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 and Mexico. For more information about Kyprolis, visit www.kyprolis.com.

Important Safety Information Regarding Kyprolis® (carfilzomib) for Injection
This safety information is specific to the current U.S. approved indication, which is based on Phase 2 studies.

Safety data have been evaluated in 526 patients with relapsed and/or refractory multiple myeloma who received single-agent Kyprolis. There were 37 deaths in the Phase 2 studies, or 7 percent of patients. The most common causes of death, other than disease progression, were cardiac events (5 patients), end-organ failure (4 patients) and infection (4 patients). Important warnings and precautions include cardiac arrest, congestive heart failure, myocardial ischemia, pulmonary hypertension, pulmonary complications, infusion reactions, tumor lysis syndrome, thrombocytopenia, hepatic toxicity, thrombotic thrombocytopenic purpura / hemolytic uremic syndrome (TTP/HUS), posterior reversible encephalopathy syndrome (PRES), and embryo-fetal toxicity.

Death due to cardiac arrest has occurred within a day of Kyprolis administration. Patients with New York Heart Association Class III and IV heart failure, myocardial infarction in the preceding 6 months and conduction abnormalities uncontrolled by medications were not eligible for the clinical trials. These patients may be at greater risk for cardiac complications.

Pulmonary arterial hypertension (PAH) was reported in 2 percent of patients treated with Kyprolis and was Grade 3 or greater in less than 1 percent of patients. Dyspnea was reported in 35 percent of patients enrolled in clinical trials. Grade 3 dyspnea occurred in 5 percent; no Grade 4 events and 1 death (Grade 5) was reported.

Infusion reactions, characterized by a spectrum of systemic symptoms including fever, chills, arthralgia, myalgia, facial flushing, facial edema, vomiting, weakness, shortness of breath, hypotension, syncope, chest tightness, or angina can occur immediately following or up to 24 hours after administration of Kyprolis. Administration of dexamethasone prior to Kyprolis reduces the incidence and severity of reactions. Tumor lysis syndrome (TLS) occurred following Kyprolis administration in <1 percent of patients. Patients with multiple myeloma and a high tumor burden should be considered to be at greater risk for TLS.

Thrombocytopenia following Kyprolis administration resulted in a dose reduction in 1 percent of patients and discontinuation of treatment with Kyprolis in <1 percent of patients.

Cases of hepatic failure, including fatal cases, have been reported (<1 percent). Kyprolis can cause elevations of serum transaminases and bilirubin.

Cases of thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS) including fatal outcome have been reported in patients who received KYPROLIS.

PRES, formerly termed Reversible Posterior Leukoencephalopathy Syndrome (RPLS), is a neurological disorder, which can present with seizure, headache, lethargy, confusion, blindness, altered consciousness, and other visual and neurological disturbances, along with hypertension, and the diagnosis is confirmed by neuro-radiological imaging (MRI). Cases of PRES have been reported in patients receiving KYPROLIS.

There are no adequate and well-controlled studies in pregnant women using Kyprolis. Females of reproductive potential should be advised to avoid becoming pregnant while being treated with Kyprolis.

The most common serious adverse reactions were pneumonia, acute renal failure, pyrexia and congestive heart failure. The most common adverse reactions (incidence of 30 percent or greater) observed in clinical trials of patients with multiple myeloma were fatigue, anemia, nausea, thrombocytopenia, dyspnea, diarrhea and pyrexia. Serious adverse reactions were reported in 45 percent of patients.

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

About BLINCYTO® (blinatumomab)

BLINCYTO is the first FDA-approved bispecific CD19-directed CD3 T-cell engager (BiTE®) antibody construct, and the first single-agent immunotherapy to be approved for the treatment of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Prior to approval, BLINCYTO was granted breakthrough therapy and priority review designation by the FDA.

Important U.S. Product Information

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 Reactions

- The most commonly reported adverse reactions (≥ 20%) in clinical trials were pyrexia (62%), headache (36%), peripheral edema (25%), febrile neutropenia (25%), 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 over 50 countries worldwide, including 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) and other parts of the world.

Nplate is the first FDA-approved treatment specifically for adult chronic ITP. It is also being investigated for potential use in children ages 12 months to 18 years old with persistent severe thrombocytopenia, and chemotherapy-induced thrombocytopenia (CIT).

In the U.S., Nplate is indicated for the treatment of thrombocytopenia in patients with chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than chronic ITP. Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts.

In the EU, Nplate is indicated for the treatment of splenectomized adult chronic ITP patients who are refractory to other treatments (e.g., corticosteroids, immunoglobulins). Nplate may be considered as a second-line treatment for adult non-splenectomized ITP patients for whom surgery is contraindicated.

Nplate was named as a recipient of the U.S. Prix Galien 2009 "Best Biotechnology Product" award and also received the 2009 Scrip Awards for "Best New Drug." Nplate has also been honored with numerous awards throughout the EU, including a 2010 Prix Galien in France in the category of "Drugs for Rare Diseases," and the 2011 Prix Galien in Germany in the category of "Specialist Care." In September 2010, Nplate was awarded the 2010 International Prix Galien Award, an award granted every two years which recognizes the "best of the best" selected from previous national Prix Galien award recipients.

For more information about Nplate, please visit www.Nplate.com.

Important U.S. Nplate Safety Information
The USPI for Nplate lists the following Warnings and Precautions: The risks associated with Nplate include progression of MDS to acute myelogenous leukemia (AML) in patients with MDS, thrombotic/thromboembolic complications, and lack or loss of response to Nplate. The USPI also notes that Nplate administration may increase the risk for development or progression of reticulin fiber formation within the bone marrow. In the placebo-controlled studies, headache was the most commonly reported adverse drug reaction.

Important EU Nplate Safety Information
The EU Summary of Product Characteristics for Nplate lists the following Special Warnings and Precautions: Reoccurrence of thrombocytopenia and bleeding after cessation of treatment, increased bone marrow reticulin, thrombotic/thromboembolic complications, progression of existing MDS (in patients with MDS), medication errors, loss of response to Nplate, and effects on red and white blood cells.

The most common adverse reactions observed include hypersensitivity reactions (including cases of rash, urticarial and angioedema) and headache. As with all therapeutic proteins, there is a potential for immunogenicity.

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 our business. Unless otherwise noted, Amgen is providing this information as of May 27, 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 recently announced restructuring plan. 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 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. 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.

Velcade® is a registered trademark of Millennium Pharmaceuticals, Inc.

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