Amgen Highlights Data To Be Presented At American Society of Hematology Annual Meeting

December 5, 2012

THOUSAND OAKS, Calif., Dec. 5, 2012 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present data from several studies at the 54th Annual Meeting of the American Society of Hematology (ASH) from Dec. 8-11, 2012, in Atlanta. These include updated results from a Phase 2 trial evaluating blinatumomab in B-precursor acute lymphoblastic leukemia (ALL) and data evaluating long-term use of Nplate® (romiplostim) in pediatric chronic immune thrombocytopenia (ITP).

"The research we are presenting at this year's annual meeting of the American Society of Hematology reflects Amgen's ongoing commitment to develop medicines for patients with the greatest need for treatment options," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Our data show exciting progress in fighting hematologic diseases, particularly in orphan diseases like ALL and ITP."

ABSTRACTS OF INTEREST INCLUDE:
Abstracts are currently available on the ASH website at www.hematology.org. Updated data will be presented at the meeting.

Blinatumomab (AMG 103) in B-precursor Acute Lymphoblastic Leukemia (ALL)

- **Anti-CD19 BiTE Blinatumomab Induces High Complete Remission Rate and Prolongs Overall Survival in Adult Patients with Relapsed/Refractory B-Precursor Acute Lymphoblastic Leukemia (ALL): Results from a Phase 2 Single-arm Dose-ranging Trial**
  Lead Author: Max S. Topp, Department of Internal Medicine II, Division of Hematology and Medical Oncology, Wuerzburg University Medical Center, Wuerzburg, Germany
  Abstract No. 670
  Oral Presentation: Monday, Dec. 10, 4:30 p.m. – 6:00 p.m. EST, A103, Level 1, Building A

Nplate in ITP

- **Long-Term Use of Open-Label Romiplostim in Children with Chronic/Refractory Immune Thrombocytopenia (ITP): Results from an Open-label Phase 1/2 Randomized Double-blind Placebo-controlled Study.**
  Lead Author: James B. Bussel, Department of Pediatrics, Division of Hematology, Weill Medical College of Cornell University, New York, NY
  Abstract No. 621
  Oral Presentation: Monday, Dec. 10, 4:30 p.m. – 6:00 p.m. EST, Georgia Ballroom 3, Level 3, Building C

- **Integrated Analysis of Long Term Safety in Patients (pts) with Chronic Immune Thrombocytopenia (ITP) Treated with Romiplostim: Results from a Safety Analysis of Pooled Data from ITP Romiplostim Clinical Studies**
  Lead Author: Douglas B. Cines, Pathology and Laboratory Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA
  Abstract No. 2185
  Poster Presentation: Sunday, Dec. 9, 6:00 p.m. – 8:00 p.m. EST, Hall B1-B2, Level 1, Building B

- **A Systematic Literature Review and Meta-Analysis of the Risk of Thromboembolic Events in Patients with Immune Thrombocytopenia (ITP) in Observational Studies: Results from a Systematic Review and Meta-Analysis of Randomized Controlled Trials of Thrombopoietin-receptor Agonists (TPOr)**
  Lead Author: Wendy Langeberg, Amgen, Thousand Oaks, CA
  Abstract No. 2187
  Poster Presentation: Sunday, Dec. 9, 6:00 p.m. – 8:00 p.m. EST, Hall B1-B2, Level 1, Building B

- **Romiplostim for the Treatment of Adults with Primary Immune Thrombocytopenia (ITP) in Routine Clinical Practice – Interim Results From a Large, European, Observational Study**
  Lead Author: Dominik Selleslag, Department of Hematology, AZ St-Jan, Brugge, Belgium
  Abstract No. 3316
  Poster Presentation: Monday, Dec. 10, 6:00 p.m. – 8:00 p.m. EST, Hall B1-B2, Level 1, Building B

Nplate in Myelodysplastic Syndromes (MDS)

- **Treatment with the Thrombopoietin (TPO)-Receptor Agonist Romiplostim in Thrombocytopenic Patients (Pts) with Low or Intermediate-1 (int-1) Risk Myelodysplastic Syndrome (MDS): Follow-up AML and Survival Results of a Randomized, Double-Blind, Placebo (PBO)-Controlled Study**
  Lead Author: Hagop M. Kantarjian, Department of Leukemia, The University of Texas MD Anderson Cancer Center, Houston, TX
  Abstract No. 421
  Oral Presentation: Monday, Dec. 10, 10:30 a.m. – 12:00 p.m. EST, B216-B217, Level 2, Building B

- **Development and Validation of a Model to Predict Response to Romiplostim in Patients With Lower-Risk Myelodysplastic Syndromes (MDS): Results from a Placebo-controlled Study**
  Lead Author: Mikkael A. Sekeres, Department of Translational Hematology and Oncology Research, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH
  Abstract No. 2801
  Poster Presentation: Sunday, Dec. 9, 6:00 p.m. – 8:00 p.m. EST, Hall B1-B2, Level 1, Building B

Febrile Neutropenia Data

- **Clinical and Economic Burden During Hospitalizations Among Cancer Patients with Febrile Neutropenia: Evidence From U.S. Hospitals, 2007-2010**
  Lead Author: Brian Dulisse, Premier Healthcare Alliance, Charlotte, NC
  Abstract No. 239
  Oral Presentation: Sunday, Dec. 9, 4:30 p.m. – 6:00 p.m. EST, C211-C213, Level 2, Building C

About Acute Lymphoblastic Leukemia (ALL)
Acute lymphoblastic leukemia (ALL) is an aggressive cancer of the blood and bone marrow — the spongy tissue inside bones where blood cells are made. The disease progresses rapidly and affects immature blood cells, rather than mature ones.[1] Worldwide, ALL accounts for more than 12 percent of leukemia. Of the 42,000 people diagnosed worldwide, 31,000 will die from the disease.[2] Patients with ALL have abnormal white blood cells (lymphocytes) that crowd out healthy white blood cells, red blood cells and platelets, and can lead to serious side effects such as infection, anemia (fatigue), and easy bleeding.[3,4]

About Blinatumomab (AMG 103)
Blinatumomab (AMG 103) has received orphan drug designation from the U.S. Food and Drug Administration (FDA) and is currently being investigated for the treatment of ALL and non-Hodgkin's lymphoma. Blinatumomab is a bispecific T cell engager (BiTE®) antibody. BiTE antibodies are designed to engage two different targets simultaneously. This dual binding ability allows BiTE antibodies to act as bridges between T cells (a type of white blood cell capable of killing other cells perceived as threats) and tumor cells. BiTE antibodies place the T cells within reach to inject toxins into the tumor cell, triggering the cell to die through apoptosis. Blinatumomab is designed to direct the T cells to target cells expressing CD19, a protein found on the surface of most B cell derived leukemias and lymphomas.

About Immune Thrombocytopenia (ITP)
In patients with immune thrombocytopenia (ITP), platelets – blood elements needed to prevent bleeding – are destroyed by the patient's own immune system. Low platelet counts leave 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.[5] 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 also unable to compensate for low levels of platelets in the blood.[6] In the United States and Europe combined, ITP is estimated to affect 50 to 100 new persons per million annually, with half of the new cases diagnosed in children.[7] ITP affects about twice as many adult women as men.[8]

About Nplate® (romiplostim)
Nplate® (romiplostim) 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.

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.

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

Important Safety Information
The risks associated with Nplate include progression of MDS to acute myelogenous leukemia (AML) in patients with MDS, thrombotic/thromboembolic complications, bone marrow reticulin formation and risk for bone marrow fibrosis, worsened thrombocytopenia after cessation of Nplate, and lack or loss of response to Nplate. Medication errors including overdose and underdose have been reported in patients receiving Nplate. In the placebo-controlled studies, headache was the most commonly reported adverse drug reaction.

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, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com. Follow us on www.twitter.com/amgen.

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. 5, 2012, 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 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 routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, the discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Further, the scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (FDA) for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses. Only the FDA can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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

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