Amgen Highlights New Data In The Treatment Of Blood Cancers At ASH 2014

November 6, 2014

Presentations Including Pivotal Data on Kyprolis® and Blinatumomab, a BiTE® Immunotherapy, Demonstrate Company's Continued Commitment to Developing Treatments for Difficult-to-Treat Blood Cancers

THOUSAND OAKS, Calif. and SOUTH SAN FRANCISCO, Calif., Nov. 6, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and its subsidiary, Onyx Pharmaceuticals, Inc., today announced that more than 50 abstracts from the Company's oncology and hematology portfolios have been accepted for presentation at the 56th Annual Meeting and Exposition of the American Society of Hematology (ASH) being held Dec. 6 – 9, 2014, in San Francisco.

Presentations include data from the pivotal trial of Kyprolis® (carfilzomib) for Injection in relapsed multiple myeloma, and blinatumomab studies in adult acute lymphoblastic leukemia (ALL) and relapsed/refractory diffuse large B-cell lymphoma (DLBCL). Additional data will be presented evaluating oprozomib in multiple myeloma and Waldenström macroglobulinemia, AMG 330 in acute myeloid leukemia (AML), and an analysis of Onyx's patient support and services program Onyx Pharmaceuticals 360™ (Onyx 360).

"The presentations at ASH demonstrate our commitment to taking on the toughest challenges in hematology and oncology by developing innovative treatments for patients with difficult-to-treat blood cancers," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "These data demonstrate Amgen's commitment to advancing scientific knowledge to improve patient care."

A full list of Amgen abstracts is currently available on the ASH website at: https://ash.confex.com/ash/2014/webprogram/start.html.

Notable abstracts of interest:

Kyprolis® (carfilzomib) for Injection
Results will be presented from ASPIRE, a randomized, open-label, multicenter Phase 3 study comparing carfilzomib, lenalidomide, and dexamethasone to lenalidomide, and dexamethasone in patients with relapsed multiple myeloma.

- **Carfilzomib, Lenalidomide, and Dexamethasone vs. Lenalidomide and Dexamethasone in Patients with Relapsed Multiple Myeloma: Interim Results from ASPIRE, a Randomized, Open-Label, Multicenter Phase 3 Study**
  Abstract # 79, Oral Presentation, Sunday, December 7, 12:00 p.m. PT (Session: 12:00-1:30 p.m. PT), West Building, 2001-2003-2014-2016

BiTE® Antibody Constructs (blinatumomab and AMG 330)
Data on two investigational bispecific T cell engager (BiTE®) antibody constructs, blinatumomab and AMG 330, will be presented at ASH. BiTE® antibody constructs represent an innovative immunotherapy approach that helps the body's immune system target cancer cells.

Key data on blinatumomab include two analyses from Study '211, a pivotal Phase 2 trial in patients with ALL; results from BLAST, a confirmatory single-arm, Phase 2 study in patients with minimal residual disease positive ALL; and long-term follow-up data from Study '206, an exploratory Phase 2 study in patients with relapsed/refractory B-precursor ALL.

- **Allogeneic Hematopoietic Stem Cell Transplantation Following anti-CD19 BiTE® Blinatumomab in Adult Patients with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia**
  Abstract # 965, Poster Presentation, Saturday, December 6, 5:30-7:30 p.m. PT, North Building, Hall E
- **An Evaluation of Molecular Response in a Phase 2 Open-Label, Multicenter Confirmatory Study in Patients With Relapsed/Refractory B-Precursor Acute Lymphoblastic Leukemia Receiving Treatment with the BiTE® Antibody Construct Blinatumomab**
  Abstract # 3704, Poster Presentation, Monday, December 8, 6:00-8:00 p.m. PT, North Building, Hall E
- **BLAST: A Confirmatory, Single-Arm, Phase 2 Study of Blinatumomab, a Bispecific T-Cell Engager (BiTE®) Antibody Construct, in Patients With Minimal Residual Disease B-Precursor Acute Lymphoblastic Leukemia**
  Abstract # 379, Oral Presentation, Monday, December 8, 10:30 a.m. PT, (Session: 10:30 a.m.-12:00 p.m. PT), West Building, 3009-3011-3022-3024
- **Long-term Survival in Adult Patients with Relapsed/Refractory B-Precursor Acute Lymphoblastic Leukemia who Achieved Minimal Residual Disease Response Following Anti-CD19 BiTE® Blinatumomab**
  Abstract # 2287, Poster Presentation, Sunday, December 7, 6:00-8:00 p.m. PT, North Building, Hall E
- **Treatment of Relapsed/Refractory Diffuse Large B-Cell Lymphoma with the Bispecific T-Cell Engager (BiTE®) Antibody Construct Blinatumomab: Primary Analysis Results From an Open-Label, Phase 2 Study**
  Abstract # 4460, Poster Presentation, Monday, December 8, 6:00-8:00 p.m. PT, West Building, Level 1

Key data on AMG 330 include three preclinical studies evaluating its potential as a therapeutic agent in AML.

- **The Broad Activity of the CD33/CD3 Bispecific BiTE® Antibody AMG 330 in Primary Human AML is Impacted By Disease Stage and Cytogenetic/Molecular Risk**
  Abstract # 266, Oral Presentation, Monday, December 8, 7:15 a.m. PT (Session: 7:00-8:30 a.m. PT), South Building,

Esplanade 301

- **Hydroxyurea is Most Suitable for Cytoreduction of AML Prior to CD33/CD3 Bispecific BiTE® Antibody (AMG 330) Therapy: Uncompromised T-Cell Proliferation Ex-Vivo and CD33 Upregulation on AML Cells**
  Abstract # 986, Poster Presentation, Saturday, December 6, 5:30-7:30 p.m. PT, North Building, Hall E
- **PD-1/PD-L1 Blocking Enhances CD33/CD3-Bispecific BiTE® Antibody (AMG 330) Mediated Lysis of Primary AML Cells**
  Abstract # 3738, Poster Presentation, Monday, December 8, 6:00-8:00 p.m. PT, North Building, Hall E

Oprozomib
Results will be presented from two Phase 1b/2 studies, including one trial evaluating oprozomib in adult patients with hematologic malignancies who have relapsed after receiving ≥1 line of therapy and another trial in patients with a form of non-Hodgkin's lymphoma. Oprozomib was recently granted orphan drug designation for the treatment of Waldenström macroglobulinemia and multiple myeloma.

- **Clinical Profile of Single-Agent Oprozomib in Patients With Multiple Myeloma: Updated Results From a Multicenter, Open-Label, Dose Escalation Phase 1b/2 Study**
  Abstract # 34, Oral Presentation, Saturday, December 6, 12:45 p.m. PT (Session: 12:00-1:30 p.m. PT), West Building, 2001-2003-2014-2016
- **Updated Results From a Multicenter, Open-Label, Dose-Escalation Phase 1b/2 Study of Single-Agent Oprozomib in Patients With Waldenström Macroglobulinemia**
  Abstract # 1715, Poster Presentation, Saturday, December 6, 5:30-7:30 p.m. PT, West Building, Level 1

Onyx Pharmaceuticals 360™ (Onyx 360)
Onyx Pharmaceuticals and Cancer Support Community established an integrated patient assistance program, Onyx 360, to screen and refer patients/caregivers facing advanced multiple myeloma for psychosocial services. Results will be reported evaluating the impact of distress screening on the utilization of resources offered by Onyx 360 and the effect of these resources on patient distress levels over time.

- **Impact of a Patient-Access Program with Integrated Distress Screening on Resource Utilization and Psychosocial Distress Levels in Patients with Multiple Myeloma**
  Abstract # 1319, Poster Presentation, Saturday, December 6, 5:30-7:30 p.m. PT, North Building, Hall E

About Kyprolis® (carfilzomib) for Injection
On July 20, 2012, the U.S. Food and Drug Administration (FDA) granted accelerated approval of Kyprolis® (carfilzomib) for Injection 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 marketed in the U.S. by Onyx Pharmaceuticals, Inc., an Amgen subsidiary.

Important Safety Information Regarding Kyprolis® (carfilzomib) for Injection
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% of patients. The most common causes of death, other than disease progression, were cardiac (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 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% of patients treated with Kyprolis and was Grade 3 or greater in less than 1% of patients. Dyspnea was reported in 35% of patients enrolled in clinical trials. Grade 3 dyspnea occurred in 5%; 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% 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% of patients and discontinuation of treatment with Kyprolis in < 1% of patients.

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

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% 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% of patients.

Full prescribing information is available at http://www.kyprolis.com.

About BiTE® Technology

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 malignant cells. 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 cancer cell to die (apoptosis). BiTE® antibody constructs are currently being investigated for their potential to treat a wide variety of cancers. For more information, visit www.biteantibodies.com.

About Blinatumomab

Blinatumomab is an investigational BiTE® antibody construct designed to direct the body's cell-destroying T cells against target cells expressing CD19, a protein found on the surface of B-cell derived leukemias and lymphomas. Blinatumomab, the first of the investigational BiTE® antibody constructs, has received orphan drug designation from the FDA and European Medicines Agency (EMA), and breakthrough therapy and priority review designation from the FDA for the treatment of ALL. The FDA has accepted for review the Biologics License Application (BLA) for blinatumomab, and a Marketing Authorization Application (MAA) has been submitted to the EMA via the centralized procedure for approval to market blinatumomab for the treatment of adults with Ph- relapsed/refractory B-precursor ALL. Blinatumomab has also received orphan drug designation from the FDA for the treatment chronic lymphocytic leukemia (CLL), hairy cell leukemia, prolymphocytic leukemia and indolent B-cell lymphoma and from the EMA for the treatment of indolent B-cell lymphoma, CLL and mantle cell leukemia (MCL). Blinatumomab is also being investigated for its potential to treat pediatric relapsed/refractory ALL, relapsed/refractory Philadelphia positive (Ph+) B-precursor ALL, minimal residual disease positive (MRD+) B-precursor ALL, relapsed/refractory non-Hodgkin's lymphoma (NHL), including relapsed/refractory diffuse large B-cell lymphoma (DLBCL).

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 the world's largest independent biotechnology company, 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.

About Onyx Pharmaceuticals, Inc.

Based in South San Francisco, California, Onyx Pharmaceuticals, Inc., an Amgen subsidiary, is a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of people with cancer. The company is focused on developing novel medicines that target key molecular pathways. For more information about Onyx, visit the company's website at www.onyx.com. Onyx Pharmaceuticals is on Twitter. Sign up to follow our Twitter feed @OnyxPharm at http://twitter.com/OnyxPharm.

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 Nov. 6, 2014, 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. Cost savings initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced 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 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.

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