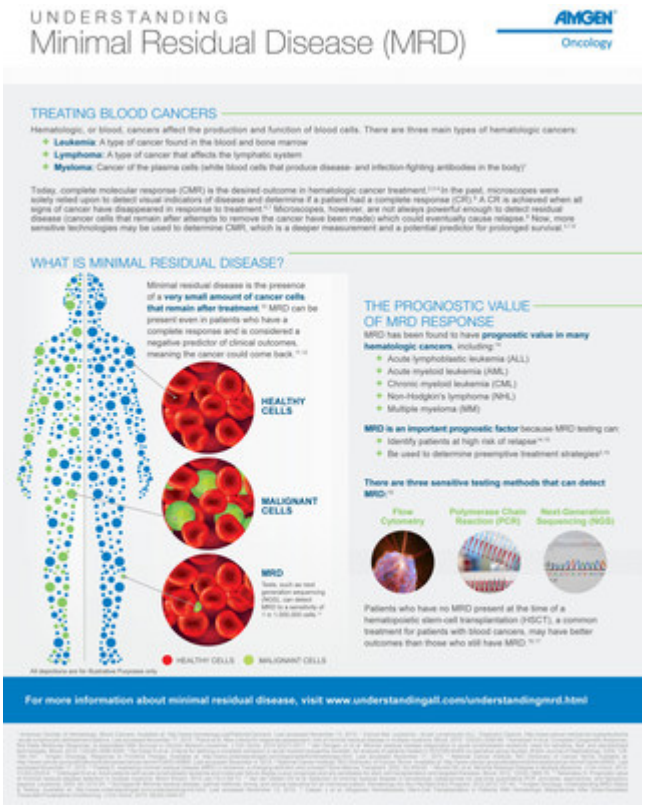
Amgen Presents Data From Three Trials Evaluating BLINCYTO® (blinatumomab) In Acute Lymphoblastic Leukemia At ASH 2015

December 7, 2015

BLINCYTO, Only Bispecific T Cell Engager (BiTE®) Immunotherapy Approved in US and EU, Shows Benefit in Phase 2 Trial in Patients With Persistent or Recurrent Minimal Residual Disease (MRD)
Data Show Positive Outcomes in Difficult-to-Treat Patient Subpopulations

THOUSAND OAKS, Calif., Dec. 7, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that new data from three Phase 2 trials support the efficacy and safety of BLINCYTO® (blinatumomab) in adults with acute lymphoblastic leukemia (ALL). These data were presented today in oral sessions at the 57th Annual Meeting and Exposition of the American Society of Hematology (ASH) in Orlando, Fla.



In a Phase 2 confirmatory multicenter single-arm trial (BLAST), adult patients with B-cell precursor ALL with minimal residual disease (MRD) who received BLINCYTO monotherapy demonstrated clinically meaningful relapse-free survival (RFS), as measured in the key secondary endpoint (abstract #680). Median RFS was 18.9 months following initiation of BLINCYTO. MRD refers to the presence of leukemia blast cells below the limits of detection available with standard assessment. Results from the Phase 2 BLAST trial were nominated for inclusion in the Best of ASH Session on Tuesday, Dec. 8 from 11:30 a.m. - 1 p.m. ET.

Other presentations demonstrate BLINCYTO's potential in a high risk subpopulation of patients with relapsed or refractory Philadelphia chromosome-positive (Ph+) B-precursor ALL (abstract #679) and confirm BLINCYTO's efficacy in a subset of patients with relapsed or refractory Philadelphia chromosome-negative (Ph-) ALL after an allogeneic hematopoietic stem cell transplantation (alloHSCT), who typically have poor outcomes with current therapies (abstract #861).

"A key goal in the treatment of blood cancers is to prevent relapse from occurring," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Achieving a complete minimal residual disease, or MRD response, is important because having no detectable MRD places ALL patients at a lower risk for relapse when compared to patients with persistent or recurrent MRD. The data presented are highly encouraging because they support the potential of BLINCYTO in a broader spectrum of ALL patients, including those at an earlier stage of disease."

ALL is a rare and rapidly progressing cancer of the blood and bone marrow.[1,2] In adult patients with relapsed or refractory ALL, median overall survival (OS) is just three to five months.[3] Currently, there is no broadly accepted standard treatment regimen for adult patients with relapsed or refractory ALL beyond chemotherapy.[4] Around 15-30 percent of adult ALL patients are Ph+ and these patients typically have a poor response to standard therapy, short remission duration and low survival rates.[5]

Abstracts are currently available on the ASH website.

ASH Abstract #680: Long-Term Outcomes After Blinatumomab Treatment: Follow-up of a Phase 2 Study in Patients With Minimal Residual

Disease (MRD) Positive B-cell Precursor ALL

- In this long-term follow up from the Phase 2 '203 study of 116 patients with B-precursor ALL and persistent or recurrent MRD after first-line chemotherapy, patients who achieved an MRD complete response with BLINCYTO had a longer OS, RFS and duration of remission (DOR) compared with those not achieving an MRD complete response, with a median OS in MRD-negative patients of 40.4 months. In data reported at ASH 2014, treatment with BLINCYTO resulted in complete MRD response in cycle 1 in 78 percent of patients.
- The most clinically relevant adverse events (AEs) were neurologic events, including tremor (30 percent), aphasia (13 percent), dizziness (8 percent), ataxia and paresthesia (6 percent each), and encephalopathy (5 percent). Rates decreased over time (cycles 1, 2, 3 and 4) for any neurologic event (47 percent, 24 percent, 15 percent and 15 percent) and any grade 3 or higher neurologic event (10 percent, 4 percent, 0 percent and 0 percent).

ASH Abstract #679: 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)

- In the Phase 2 ALCANTARA study, BLINCYTO showed antileukemic activity in very poor prognosis patients with relapsed or refractory Ph+ B-precursor ALL after failure of at least one second-generation tyrosine kinase inhibitor (TKI) therapy, with 36 percent of patients achieving complete remission or complete remission with partial hematological recovery (CR/CRh) during the first two treatment cycles. Of patients who achieved CR/CRh, 88 percent achieved a complete MRD response. Equivalent response rates were observed in patients with kinase-domain mutations in BCR-ABL such as T315I (four achieved CR/CRh; all four also achieved a complete MRD response).
- Patient incidence of grade 3 or higher treatment-emergent AEs was 82 percent, most commonly febrile neutropenia (27 percent), thrombocytopenia (22 percent), anemia (16 percent), pyrexia (11 percent) and neurologic events (7 percent). There were no episodes of grade 3 or higher cytokine release syndrome.

ASH Abstract #861: 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

- In this analysis from the pivotal Phase 2 '211 trial, BLINCYTO induced a CR/CRh rate of 45 percent in a subset of 64 heavily pretreated patients with Ph- ALL who had relapsed or were refractory after an alloHSCT.
- In total, 88 percent of patients had grade 3 or higher treatment-emergent AEs, with the most frequent including neutropenia (22 percent), febrile neutropenia (20 percent), anemia (17 percent) and thrombocytopenia (14 percent). Six patients reported treatment-emergent graft vs. host disease (GvHD), two of which were grade 3 or higher.

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 BLINCYTO® (blinatumomab)

BLINCYTO is a bispecific CD19-directed CD3 T cell engager (BiTE®) antibody construct that binds specifically to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T cells. BLINCYTO was granted breakthrough therapy and priority review designations by the U.S. Food and Drug Administration, and is now approved in the U.S. for the treatment of 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.

About BiTE® Technology

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.

BLINCYTO® U.S. Product Safety Information

Important Safety Information Regarding BLINCYTO® (blinatumomab) U.S. Indication

This safety information is specific to the current U.S. approved indication.

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 have been 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 with BLINCYTO® treatment. 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%), diarrhea (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.

U.S. 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 U.S. Prescribing Information and medication guide for BLINCYTO® at www.BLINCYTO.com.

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.

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 malignances, ranging from blood cancers to solid tumors. With decades of experience providing treatments for cancer patients, Amgen continues to grow its portfolio of innovative and biosimilar oncology medicines.

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 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 Dec. 07, 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 Amgen and its partners routinely obtain patents for 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 their ability to pay a dividend or repurchase our 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.

CONTACT: Amgen, Thousand Oaks
Kristen Davis, 805-447-3008 (Media)
Kristen Neese, 805-313-8267 (Media)
Arvind Sood, 805-447-1060 (Investors)

References:

1. Cancer Research UK. Acute lymphoblastic leukaemia risks and causes. _http://www.cancerresearchuk.org/about-cancer

/type/all/about/acute-lymphoblastic-leukaemia-risks-and-causes. Accessed September 29, 2015.
2. Mayo Clinic. "Acute lymphocytic leukemia." Available at: _http://www.mayoclinic.com/health/acute-lymphocytic-leukemia/DS00558. Accessed on March 5, 2015.
3. Advani A.S. New immune strategies for the treatment of acute lymphoblastic leukemia: Antibodies and chimeric antigen receptors. Hematology Am Soc Hematol Educ Program. 2013;2013:131-7. Retrieved from: _http://asheducationbook.hematologylibrary.org/content/2013/1/131.long.
4. Davis T and Farag SS. Treating relapsed or refractory Philadelphia chromosome-negative acute lymphoblastic leukemia: liposome-encapsulated vincristine. Int J Nanomedicine. 2013:8 3479-3488.
5. Faderl S et al. Outcome of Philadelphia chromosome-positive adult lymphoblastic leukemia. Leukemia and Lymphoma. 2000;36(3-4):263-273.

Photo - http://photos.prnewswire.com/prnh/20151207/293533-INFO

Logo - http://photos.prnewswire.com/prnh/20081015/AMGENLOGO