Amgen and MD Anderson Announce Agreement to Develop BiTE® Therapies for Myelodysplastic Syndrome

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MD Anderson's Moon Shots Program key to Collaboration

THOUSAND OAKS, Calif. and HOUSTON, Jan. 12, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) and The University of Texas MD Anderson Cancer Center today announced a research collaborative agreement focusing on Amgen's bispecific T cell engager (BiTE®) antibody constructs, an immunotherapy that serves as a "bridge" between T cells and cancer cells.

The research agreement will identify targets for this therapy in myelodysplastic syndrome (MDS), a bone marrow disorder in which the body does not produce sufficient healthy blood cells. MDS affects primarily older adults over age 60 and can cause severe anemia, potentially leading to development of acute myelogenous leukemia (AML), a blood cell cancer.

"This is a unique collaboration that explores BiTE® therapy for its potential in treating a disorder that affects thousands of people each year," said Guillermo Garcia-Manero, M.D., professor of leukemia at MD Anderson. "At MD Anderson, we have unrivaled proteomics capabilities to explore new targets for this disease, and this novel approach may very well open up new potential treatments for our patients."

The collaboration's innovative approach will draw on the expertise of MD Anderson's Moon Shots Program, which aims to accelerate the conversion of scientific discoveries into clinical advances and significantly reduce cancer deaths. Garcia-Manero leads the MDS/AML Moon Shots Program.

The collaborative agreement will allow Amgen and MD Anderson to join forces in a research partnership that aims to take new drug development from "A to Z." The agreement provides for joint development of new agents under pre-determined terms. Amgen retains all commercial rights, while MD Anderson is eligible to receive milestones and royalties upon successful achievement of key objectives.

"We are excited about the new research opportunities this collaboration will open up in further exploring the potential of BiTE® technology," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "BiTE® antibody constructs represent an innovative immunotherapy approach that helps the body's immune system target cancer cells. MD Anderson is a great partner in our quest to find potential new treatments for patients with serious illnesses."

BiTE® antibody constructs are recombinant proteins consisting of two separate antibodies held together by a flexible peptide linker or bands of amino acids. The antibodies are designed to function as a link between T cells and cancer cells. One antibody or protein domain binds to the cancer cell's surface, while the other binds to the CD3 on the T cell, resulting in the malignant cell's death. It is thought that BiTE® antibody constructs may be engineered to target a range of tumors.

"This long-term collaboration between leading scientists at MD Anderson and Amgen takes advantage of significant advances in technologies available for target discovery through the MD Anderson Moon Shots Program," said Samir Hanash, M.D., Ph.D., professor of clinical cancer prevention and director, the Red and Charline McCombs Institute for the Early Detection and Treatment of Cancer at MD Anderson. "The agreement covers the full scope of clinical development from identifying targets for this therapy in MDS to developing fully tested and approved new therapies."

About MD Anderson
The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. MD Anderson is one of only 41 comprehensive cancer centers designated by the National Cancer Institute (NCI). For the past 25 years, MD Anderson has ranked as one of the nation's top two cancer centers in U.S. News & World Report's annual "Best Hospitals" survey. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

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 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.

On Dec. 3, 2014 the U.S. Food and Drug Administration (FDA) granted approval of BLINCYTO ™(blinatumomab) for the treatment of patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). This indication was approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials. With this

approval, BLINCYTO becomes the first FDA-approved bispecific CD19-directed CD3 T cell engager (BiTE®) antibody construct product, and the first single-agent immunotherapy to be approved for the treatment of patients with Ph- relapsed or refractory B-cell precursor ALL, a rare and rapidly progressing cancer of the blood and bone marrow.[1-3]

BLINCYTO has a **BOXED WARNING** in its product label regarding Cytokine Release Syndrome (CRS) and Neurological Toxicities.

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

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

Monitor patients for signs and symptoms of infection and treat appropriately.

Advise patients to refrain from driving and engaging in hazardous occupations or activities such as driving, operating heavy or potentially dangerous machinery while BLINCYTO is being administered.

It is important to strictly follow instructions for preparation (including admixing) and administration to prevent overdose and underdose.

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

The FDA has also approved a risk evaluation and mitigation strategy (REMS) for BLINCYTO. The purpose of the BLINCYTO REMS is to inform healthcare providers of the serious risks of CRS, neurological toxicities, and preparation and administration errors. Additional information about the BLINCYTO REMS program can be found at http://www.BLINCYTOREMS.com.

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) 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 Jan. 12, 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 Amgen projects. 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 Amgen and its partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development.

In addition, sales of Amgen's products (including products of Amgen's 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 Amgen's products. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. In addition, while Amgen and its partners routinely obtain patents for their products and technology, the protection of Amgen's products offered by patents and patent applications may be challenged, invalidated or circumvented by its competitors and there can be no guarantee of Amgen's or its partners' ability to obtain or maintain patent protection for Amgen's products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations. Amgen's efforts to integrate the operations of companies it has acquired may not be successful. Cost savings initiatives may result in Amgen incurring impairment or other related charges on Amgen's assets. Amgen may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from its recently announced restructuring plans. Amgen's business performance could affect or limit the ability of Amgen's Board of Directors to declare a dividend or Amgen's 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.

CONTACT: Amgen, Thousand Oaks
Cuyler Mayer, 805-447-6332 (Amgen media)
Arvind Sood, 805-447-1060 (investors)

CONTACT: MD Anderson
Ron Gilmore, 713-745-1898
rlgilmore@mdanderson.org

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