

Amgen To Present New Pre-Clinical Data Showcasing Robust Approach To Evaluating Potential Anti-Cancer Therapies At AACR 2018

April 9, 2018

First Data Presentations for CAR T Programs, Including DLL3 in Small Cell Lung Cancer and FLT3 in Acute Myeloid Leukemia Pre-Clinical Data Evaluating Half-Life Extended Anti-BCMA BiTE® Presented for First-Time

Pre-Clinical Data Evaluating Half-Life Extended Anti-BCMA BiTE® Presented for First-Time New Data Include two Studies Investigating McI-1 Inhibitor AMG 176

THOUSAND OAKS, Calif., April 9, 2018 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that new pre-clinical data for several of its novel investigational oncology candidates will be presented at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, April 14-18, 2018. Data spans Amgen's early pipeline, including the first presentation of data for its most advanced chimeric antigen receptor (CAR) T cell therapy programs, targeting DLL3 in small cell lung cancer and FLT3 in acute myeloid leukemia (AML). In addition, pre-clinical data for Amgen's DLL3 CAR T cell therapy and bispecific T cell engager (BiTE[®]) program will be featured in an oral presentation.

"As part of our overarching research and development strategy, Amgen is committed to advancing multiple modalities to gain biological insights before selecting the optimal treatment approach," said David M. Reese, M.D., senior vice president of Translational Sciences and Oncology at Amgen. "With a variety of tools in our toolkit, we have the ability to comprehensively evaluate these novel approaches to determine how each may perform in different treatment settings. We look forward to seeing how the pre-clinical data ultimately translate in the clinic."

Research presented at the meeting will also include pre-clinical studies examining pharmacodynamic markers for Mcl-1 inhibition, as well as the combination of Amgen's Mcl-1 inhibitor (AMG 176) with a selective BCL-2 inhibitor in models of AML. AMG 176 is a highly selective and reversible Mcl-1 inhibitor and is being studied in a Phase 1 clinical trial involving patients with relapsed or refractory AML or multiple myeloma. Studies have shown that hematologic malignancies including AML, multiple myeloma and non-Hodgkin lymphoma are particularly sensitive to Mcl-1 inhibition.

In addition, Amgen will present for the first time pre-clinical data evaluating its half-life extended (HLE) anti-BCMA BiTE[®] for the treatment of multiple myeloma. A phase 1 study evaluating Amgen's anti-BCMA HLE-BiTE[®] (AMG 701) is ongoing.

With the exception of late-breaking research, abstracts are available and can be reviewed on the AACR website at <u>http://www.aacr.org/</u>. Identified below are select abstracts of interest on Amgen research:

Immuno-oncology

- Targeting DLL3 with BiTE[®] antibody constructs and cell-based therapies for the treatment of SCLC Abstract #DDT02, Oral Presentation, Sunday, April 15 from 3:24-3:48 p.m. CT at McCormick Place South (Level 1), Room S103
- Generation and evaluation of a FLT3 CAR-T cell therapy for the treatment of acute myeloid leukemia Abstract #2559/18, Poster Session, Monday, April 16 from 1-5 p.m. CT at McCormick Place, Exhibit Hall A, Poster Section 24
- Cynomolgus monkey plasma cell gene signature to quantify the *in vivo* activity of a half-life extended anti-BCMA BiTE[®] for the treatment of multiple myeloma

Abstract #LB-299/21, Poster Presentation, Tuesday, April 17 from 1-5 p.m. CT at McCormick Place, Exhibit Hall A, Poster Section 44

Mcl-1 Inhibition

• The utilization of a human MCL-1 knock-in mouse suggests that reductions in B-cells and monocytes may serve as clinically relevant pharmacodynamic markers of MCL-1 inhibition

Abstract #2978, Oral Presentation, Monday, April 16 from 4:35-4:50 p.m. CT at McCormick Place North (Level 4), Room N427

• Combined inhibition of MCL-1 and BCL-2 with AMG 176 and venetoclax induces apoptosis and tumor regression in models of acute myeloid leukemia

Abstract #3972/6, Poster Session, Tuesday, April 17 from 8 a.m.-noon CT at McCormick Place, Exhibit Hall A, Poster Section 41

About CAR T Cell Therapy

CAR T cell therapy is an evolving area of personalized medicine in which a patient's own T cells (a type of white blood cell) are engineered to recognize tumor-specific antigens and incite an immune system attack against the cancer cells. Amgen is exploring the application of CAR T cell therapy across hematologic and solid tumor malignancies. Amgen and Kite Pharma, a subsidiary of Gilead Sciences Inc., are collaborating on engineering and commercializing Car T cell therapies.

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 bridge T cells to tumor cells, using the patient's own immune

system to eradicate cancer. 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.

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

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 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. 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 reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. 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, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and 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. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. 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. Further, 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, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. 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 our 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, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

CONTACT: Amgen, Thousand Oaks Kristen Davis, 805-447-3008 (media)



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