

Amgen To Highlight New Preclinical Data At The American Association For Cancer Research (AACR) Annual Meeting

March 31, 2017

Preclinical Results for McI-1 Inhibitor for Multiple Myeloma Accepted as Oral Presentation New Data on Bispecific T Cell Engagers (BiTE®) Immunotherapy Platform Preclinical Study Combining Different Immuno-Oncology Agents

THOUSAND OAKS, Calif., March 31, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that new preclinical data from its oncology portfolio will be presented at the American Association for Cancer Research (AACR) Annual Meeting from April 1-5, 2017, in Washington, D.C. These data provide insights into the potential of Amgen's half-life optimized bispecific T cell engager (BiTE[®]) immunotherapy platform across different cancers, as well as the local and systemic immune effects from combining Amgen's oncolytic virus with a CTLA-4 inhibitor.

Preclinical data from Amgen's latest oncology candidate to enter clinical trials (AMG 176) will also be presented. AMG 176 is a potent, highly selective and reversible Mcl-1 inhibitor. A variety of studies have demonstrated that hematologic malignancies, such as multiple myeloma, acute myeloid leukemia and non-Hodgkin lymphoma, are particularly sensitive to Mcl-1 inhibition.

"AACR has always been an important meeting for sharing some of our latest advances in cancer research and 2017 is no exception. This year's data underscores our commitment to Amgen's evolving oncology portfolio and to the discovery and development of innovative new therapies," said David Reese, M.D., senior vice president of Discovery Research (interim) and Translational Sciences at Amgen. "In addition to sharing new data for some of our more advanced compounds, we also look forward to sharing research around our first-in-class Mcl-1 inhibitor, a small molecule being investigated for its potential use in patients with hematologic malignancies for which there continues to be a need for new treatment options."

Abstracts are available and can be viewed on the AACR website at <u>http://www.aacr.org/</u>. Identified below are selected abstracts of interest on Amgen research.

Mcl-1 Inhibition:

• The discovery and preclinical characterization of AMG 176: A first-in-class McI-1 inhibitor in clinical development for multiple myeloma

Abstract #DDT01-01, Oral Presentation, Sunday, April 2 from 1–1:24 p.m. ET at Walter E. Washington Convention Center, East Salon A-B, Level 1

- Combined targeting of MEK and MCL-1 induces apoptosis and tumor regression of KRAS mutant NSCLC Abstract #2163, Poster Session, Monday, April 3 from 1–5 p.m. ET at Walter E. Washington Convention Center, Halls A-C, Section 7
- Preclinical evaluation of AMG 176, a novel, potent and selective McI-1 inhibitor with robust anti-tumor activity in McI-1 dependent cancer models

Abstract #2027, Poster Session, Monday, April 3 from 1–5 p.m. ET at Walter E. Washington Convention Center, Halls A-C, Section 1

BiTE[®] Antibody Construct:

- Generation of half-life extended anti-CD33 BiTE[®] antibody constructs compatible with once-weekly dosing Abstract #55, Poster Session, Sunday, April 2 from 1–5 p.m. ET at Walter E. Washington Convention Center, Halls A-C, Section 3
- Preclinical evaluation of a BiTE[®] antibody construct with extended half-life that targets the tumor differentiation marker mesothelin

Abstract #3630, Poster Session, Tuesday, April 4 from 8 a.m. – noon ET at Walter E. Washington Convention Center, Halls A-C, Section 26

• BiTE[®] antibody constructs for the treatment of SCLC

Abstract #3632, Poster Session, Tuesday, April 4 from 8 a.m. – noon ET at Walter E. Washington Convention Center, Halls A-C, Section 26

Immuno-Oncology:

 OncoVEX^{mGM-CSF} (HSV-1 modified similarly to talimogene laherparepvec) icombination with CTLA-4 blockade leads to both local and systemic efficacy in a murine syngeneic model of metastatic melanoma Abstract #4566, Poster Session, Tuesday, April 4 from 1–5 p.m. ET at Walter E. Washington Convention Center, Halls A-C, Section 25

Growth Inhibitory Pathway:

• Selective MET kinase inhibition in MET-dependent glioma models

Abstract #2077, Poster Session, Monday, April 3 from 1–5 p.m. ET at Walter E. Washington Convention Center, Halls A-C, Section 4

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 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.

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 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. 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 pavers, 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. 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. 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 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. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. 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 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 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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To view the original version on PR Newswire, visit: <u>http://www.prnewswire.com/news-releases/amgen-to-highlight-new-preclinical-data-at-the-american-association-for-cancer-research-aacr-annual-meeting-300432440.html</u>

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