Amgen Highlights Progress Of Innovative Early Oncology Pipeline With New Data At AACR 2019

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First Preclinical Data to be Presented on AMG 510, a First-in-Class KRASG12C Inhibitor for Solid Tumors
New Preclinical Data Evaluating AMG 757 to Highlight Half-Life Extended BiTE® Immunotherapy
AMG 176 Preclinical Data Showcase Potential in Combination With Standard of Care Treatments for Acute Myeloid Leukemia

THOUSAND OAKS, Calif., Feb. 28, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that new data from its early-stage oncology pipeline will be presented at the American Association for Cancer Research (AACR) Annual Meeting in Atlanta, March 29 – April 3, 2019.

"At Amgen, we are searching for and finding answers to incredibly complex questions to advance care and improve lives for cancer patients," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "In a significant milestone in the oncology community, we will share the latest preclinical data from our *KRAS*^{G12C} inhibitor, AMG 510. *KRAS* has eluded targeting despite more than 30 years of industry and academic research. Our program is the first to reach the clinical stage, which will evaluate its potential against a target that is easily identifiable and present in a wide range of solid tumors."

For the first time, preclinical data will be presented on AMG 510, a first-in-class investigational *KRAS*^{G12C} inhibitor being evaluated for the treatment of solid tumors. Data at the meeting will also showcase Amgen's novel bispecific T cell engager (BiTE®) platform, including preclinical data evaluating the use of AMG 757, a DLL3-targeted BiTE® molecule, in resistant subtypes of melanoma. Additional research to be presented will include preclinical data evaluating the use of Amgen's intravenous investigational MCL-1 inhibitor, AMG 176, in combination with standard of care therapies in acute myeloid leukemia.

A complete listing of abstracts can be found on the AACR website. Notable abstracts of interest include:

***KRAS*^{G12C} Inhibition:**

- **Discovery of AMG 510: A Noval Covalent Inhibitor of *KRAS*^{G12C}, Now in a Phase 1 Clinical Trial for Patients with Solid Tumors Harboring the *KRAS P.G12C* Allele**
  Oral Presentation, Sunday, March 31 from 4:28-4:52 p.m. ET in Georgia World Congress Center, Building A, Level 3, Room A305
- **Discovery and *In Vitro* Characterization of AMG 510, a Potent and Selective Covalent Small Molecule Inhibitor of *KRAS*^{G12C}**
  Abstract #4484, Oral Presentation, Tuesday, April 2 from 3-5 p.m. ET in Georgia World Congress Center, Building C, Level 3, Georgia Ballroom 3
- **Discovery of AMG 510, a First-In-Human Covalent Inhibitor of *KRAS*^{G12C} for the Treatment of Solid Tumors**
  Abstract #4455, Oral Presentation, Tuesday, April 2 from 3-5 p.m. ET in Georgia World Congress Center, Building B, Level 2, Room B206
- ***In Vivo* Characterization of AMG 510, A Potent and Selective *KRAS*^{G12C} Covalent Small Molecule Inhibitor in Preclinical *KRAS*^{G12C} Cancer Models**
  Abstract #3090/24, Poster Presentation, Tuesday, April 2 from 8 a.m.-noon ET in Georgia World Congress Center, Exhibit Hall B, Section 14

BiTE® Antibody Construct:

- **Melanoma Subtypes that Emerge During Adaptive Resistance to Therapy are Targets for Bispecific T Cell Engager (BiTE®) Antibody Constructs Directed to CDH19 And DLL3**
  Abstract #553/17, Poster Presentation, Sunday, March 31 from 1-5 p.m. ET in Georgia World Congress Center, Exhibit Hall B, Section 23
- **Evaluation of Mesothelin BiTE® Antibody Constructs in Models of Pancreatic Ductal Adenocarcinoma**
  Abstract #1561/30, Poster Presentation, Monday, April 1 from 8 a.m.-noon ET in Georgia World Congress Center, Exhibit Hall B, Section 25

Additional Preclinical Data:

- **AMG 176 Exhibits Robust Antitumor Activity in Combination with Standard of Care Agents in Models of Acute Myeloid Leukemia**
  Abstract #2180/2, Poster Presentation, Monday, April 1 from 1-5 p.m. ET in Georgia World Congress Center, Exhibit Hall B, Section 14
- **CSF-1 Receptor-Mediated Macrophage Depletion Can Induce Immunomodulatory Resistance Mechanisms in Murine Tumor Models**

Abstract #2803/19, Poster Presentation, Tuesday, April 2 from 8 a.m.-noon ET in Georgia World Congress Center, Exhibit Hall B, Section 3

About *KRAS*

The subject of more than three decades of research, *RAS* proteins make up the most frequently mutated gene family in human cancers.[1,2] Within this family, *KRAS* is the most prevalent variant and is particularly common in solid tumors.[2] A specific mutation known as $KRAS^{G12C}$ accounts for approximately 12 percent of all *KRAS* mutations across tumor types.[3] Amgen is exploring the potential of $KRAS^{G12C}$ inhibition across a broad variety of tumor types.

About BiTE® Technology

Bispecific T cell engager (BiTE®) antibody construct is an innovative technology that can be engineered to target any tumor antigen expressed by any type of cancer. The protein molecules are designed to kill malignant cells using the patient's own immune system by bridging T cells to tumor cells. BiTE® antibody construct helps connect the T cells to the targeted cell, with the intent of causing T cells to inject toxins which trigger cancer cell death (apoptosis). Amgen is developing BiTE® antibody constructs to uniquely (or specifically) target numerous hematologic malignancies and solid tumors.

About Amgen's Commitment to Oncology

Amgen 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.

For more information, follow us on www.twitter.com/amgenoncology.

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. 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 in 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. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. 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. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. 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. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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.

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2. Fernandez-Medarde A, Santos E. Ras in Cancer and Developmental Diseases. *Genes Cancer.* 2011;2(3):344-358.
3. Hobbs G, Wittinghofer A, Der C. Selective Targeting of the KRAS G12C Mutant: Kicking KRAS When It's Down. *Cancer Cell.* 2016;29(3):251-253.