Amgen Obtains Global Development And Commercial Rights From Boehringer Ingelheim For Investigational BiTE® Immuno-Oncology Drug For Multiple Myeloma

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THOUSAND OAKS, Calif. and INGELHEIM, Germany, Sept. 1, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Boehringer Ingelheim today announced that Amgen has acquired global development and commercial rights from Boehringer Ingelheim for BI 836909 (AMG 420), a bispecific T cell engager (BiTE®) that targets B-cell maturation antigen (BCMA), a potential target for multiple myeloma. BI 836909 (AMG 420) is currently in Phase 1 studies. BI 836909 (AMG 420) was originally licensed to Boehringer Ingelheim by Micromet before the company was acquired by Amgen in 2012.

Under the provisions of the agreement, Amgen will work with Boehringer Ingelheim to assume responsibility for the clinical development of BI 836909 (AMG 420), transfer manufacturing, and lead global regulatory activity moving forward. Amgen will also receive worldwide commercialization rights for BI 836909 (AMG 420). Prior to this agreement, Boehringer Ingelheim held global development and commercialization rights. Financial terms of the agreement are not being disclosed.

"Obtaining global rights to BI 836909 (AMG 420) advances Amgen's immuno-oncology strategy, allowing us to leverage our expertise with the BiTE® platform to target BCMA in the multiple myeloma setting," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Multiple myeloma is a rare and aggressive blood cancer and despite new advances there is currently no cure.[1-3] BI 836909 (AMG 420) allows us to explore a potential new treatment approach that harnesses the immune system to fight multiple myeloma."

"Boehringer Ingelheim is delighted that Amgen will continue our successful development of this important compound for multiple myeloma," said Dr. Jörg Barth, corporate senior vice president, Therapy Area Head Oncology at Boehringer Ingelheim. "Given Amgen's focus in this disease area, we are convinced this best supports the future development for BI 836909 (AMG 420) and the goal to ultimately offer new treatment options for patients. Immuno-oncology and T cell engagers remain a key area of focus for Boehringer Ingelheim as well as providing innovative treatments for lung and blood cancers."

About BI 836909 (AMG 420)

BI 836909 (AMG 420) is a bispecific T cell engager (BiTE®) that is under investigation for the treatment of multiple myeloma. BI 836909 (AMG 420) targets B-cell maturation antigen (BCMA), a target in multiple myeloma due to its restricted normal tissue expression and uniform expression on multiple myeloma cells. BI 836909 (AMG 420) is currently being evaluated in Phase 1 studies.

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

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.

About Boehringer Ingelheim in Oncology

Oncology is one of five key focus areas for Boehringer Ingelheim with 13 compounds in clinical development across a broad range of solid tumors and blood cancers. This includes non-small cell lung cancer, squamous cell carcinoma of the lung, acute myeloid leukemia, chronic lymphocytic leukemia and myelodysplastic syndromes. In addition, BI continues with key strategic partnerships in oncology all with a focus on improving the lives of patients with cancer.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, Boehringer Ingelheim operates globally through 145 affiliates and a total of some 47,500 employees. The focus of the family-owned company, founded in 1885, is on researching, developing, manufacturing and marketing new medications of high therapeutic value for human and veterinary medicine.

Social responsibility is an important element of the corporate culture at Boehringer Ingelheim. This includes worldwide involvement in social projects through, for example, the initiative "Making More Health" while also caring for employees. Respect, equal opportunity and reconciling career and family form the foundation of mutual cooperation. The company also focuses on environmental protection and sustainability in everything it does.

For more information please visit www.boehringer-ingelheim.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 its 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 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 to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. 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 its products after they are on the market.

Amgen's results may be affected by its 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 its products and global economic conditions. In addition, sales of Amgen's 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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between it and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key manufacturing facilities and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. 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 its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all. Amgen is increasingly dependent on information technology systems, infrastructure and data security. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock.

The scientific information discussed in this news release related to Amgen's 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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