Amgen Announces Global Diagnostic Collaborations To Expand Molecular Testing For Patients With Non-Small Cell Lung Cancer

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First Company Developing a KRAS(G12C) Inhibitor to Announce Multi-Platform Companion Diagnostics Collaborations With Guardant Health and QIAGEN Will Develop Blood- and Tissue-Based Companion Diagnostics For Investigational KRAS(G12C) Inhibitor AMG 510

KRAS G12C is Present in 13% of Non-Small Cell Lung Cancers With no Approved Targeted Treatments

THOUSAND OAKS, Calif., Jan. 13, 2020 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced strategic collaborations with leading diagnostic companies Guardant Health, Inc. and QIAGEN N.V. to develop blood- and tissue-based companion diagnostics (CDx), respectively, for investigational cancer treatment AMG 510. AMG 510 is the first $KRAS^{G12C}$ inhibitor to advance to the clinic for investigation in treatment of multiple tumor types. *KRAS G12C* is one of the most frequently mutated oncogenes in human cancers. The agreements with both companies will initially focus on CDx tests for non-small cell lung cancer (NSCLC) but allow for further development of the diagnostic tests for Amgen's other oncology clinical development programs.

"Amgen is committed to driving broad accessibility to biomarker testing in order to select appropriate patients who will directly benefit from targeted treatments," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "With one in eight patients with NSCLC having *KRAS G12C,* there's a critical need to improve access to high quality diagnostics and more routine screening. Collaborating with QIAGEN and Guardant Health to have both tissue- and blood-based diagnostic tests available will help to identify patients with NSCLC who may benefit from AMG 510."

Amgen will work with QIAGEN to develop a tissue-based diagnostic test utilizing its *therascreen*® platform to identify patients whose cancers have the *KRAS G12C* mutation. QIAGEN will also pursue global regulatory approvals, including Pre-Market Approval (PMA) from the U.S. Food and Drug Administration (FDA). To enable biomarker testing in patients for whom insufficient tissue remains a challenge, Amgen is also collaborating with Guardant Health to develop a liquid biopsy CDx. Guardant360 CDx is a multi-tumor comprehensive NGS (Next Generation Sequencing) test that is being developed to identify patients with actionable alterations, in this instance with the *KRAS G12C* mutation in NSCLC. Guardant Health will seek global regulatory approvals for the test, including a PMA from the FDA.

AMG 510 is currently enrolling patients in a potentially registrational Phase 2 study (CodeBreak ™100). The FDA granted Orphan Drug Designation to AMG 510 for previously treated metastatic NSCLC and colorectal cancer with *KRAS G12C* mutation and Fast Track Designation for previously treated metastatic NSCLC with *KRAS G12C* mutation.

Amgen established *RAS* as the first actionable biomarker in metastatic colorectal cancer and is now pioneering the development of *KRAS* mutation specific inhibitors in lung cancer and other solid tumors with AMG 510.

About *KRAS*

The subject of almost four decades of research, the *RAS* gene family are the most frequently mutated oncogenes 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* is found in approximately 13% of non-small cell lung cancers, three to five percent of colorectal cancers and one to two percent of numerous other solid tumors.[3] $KRAS^{G12C}$ has been considered "undruggable" due to a lack of traditional small molecule binding pockets on the protein.[4] Amgen is exploring the potential of $KRAS^{G12C}$ inhibition across a broad variety of tumor types.

About Amgen Oncology

Amgen Oncology is searching for and finding answers to incredibly complex questions that will advance care and improve lives for cancer patients and their families. Our research drives us to understand the disease in the context of the patient's life – not just their cancer journey – so they can take control of their lives.

For the last four decades, we have been dedicated to discovering the firsts that matter in oncology and to finding ways to reduce the burden of cancer. Building on our heritage, Amgen continues to advance the largest pipeline in the Company's history, moving with great speed to advance those innovations for the patients who need them.

At Amgen, we are driven by our commitment to transform the lives of cancer patients and keep them at the center of everything we do.

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 any statements on the outcome, benefits and synergies of collaboration with any other company, including BeiGene, Ltd., or the Otezla® (apremilast) acquisition, including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion, as well as 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 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 collaborate with or acquire other companies or products, and to integrate the operations of companies or in support of products 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. Further, any 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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