Amgen Launches Biomarker Assist™, a Program To Help More Patients With Non-Small Cell Lung Cancer Gain Access To Biomarker Testing

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Half of All Patients With NSCLC Have Oncogene Mutations, Yet Many Patients Are Not Tested to Screen for Biomarkers

Professional Clinical Guidelines Recommend Broad Biomarker Testing for Actionable and Emerging Biomarkers, Including KRAS

Biomarker Assist™ May Provide Eligible Patients Savings on Biomarker Testing

THOUSAND OAKS, Calif., April 19, 2021 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced the launch of Biomarker Assist ™, a program to help more patients with metastatic (stage IV) non-small cell lung cancer (NSCLC) gain access to biomarker testing. Biomarker testing at the time of diagnosis is a critical first step in getting patients on the right treatment. Through Biomarker Assist ™, eligible patients may save on biomarker testing.

Professional clinical guidelines, including the College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), the Association for Molecular Pathology (AMP) and the American Society of Clinical Oncology (ASCO) recommend comprehensive biomarker testing of multiple genes simultaneously—for both actionable and emerging biomarkers—for patients diagnosed with advanced NSCLC regardless of clinical characteristics such as age, race or smoking status.[1]

"Approximately half of all patients with non-small cell lung cancer have oncogene biomarkers, yet despite the integral role that biomarkers play in lung cancer to identify patients who may benefit from targeted therapies, many patients are not tested," said Darryl Sleep, M.D., chief medical officer and senior vice president of Global Medical at Amgen.[2,3] "Amgen is excited to launch Biomarker Assist ™, a patient support program that demonstrates our commitment to closing the gap in testing rates. Based on a patient's biomarker status, clinicians and patients can make informed decisions on personalized treatment plans and targeted therapies which have significantly improved the prognosis for many patients."

NSCLC is a heterogeneous disease associated with different driver mutations that are responsible for cancer development and growth.[1] There are currently seven different actionable driver mutations in NSCLC with a number of emerging therapies under investigation for other molecular mutational drivers, including *KRAS*.

"The advancement of personalized medicine has transformed the treatment of lung cancer leading to the development of innovative targeted immunotherapies and personalized treatment plans for patients," said Jennifer C. King, Ph.D., chief scientific officer of GO2 Foundation for Lung Cancer. "Over the last decade, the cancer community has learned a great deal about precision medicine, particularly for non-small cell lung cancer, but if patients aren't getting comprehensive biomarker testing, then they are less likely to benefit from all of the therapeutic advancements. We welcome programs like Amgen's Biomarker Assist ™because we need support from all stakeholders, including industry, so that comprehensive biomarker testing becomes universal for everyone who is diagnosed with lung cancer."

About Amgen Biomarker Assist ™

Biomarker Assist ™is comprised of two programs: the **Next Generation Sequencing (NGS) Affordability Program** and the ***KRAS* Single Gene Test (SGT) Program**. The NGS Affordability Program offers assistance to eligible patients with out-of-pocket costs for a comprehensive biomarker panel for patients who have advanced or metastatic (stage IV) NSCLC. This panel must include the *KRAS* gene. The program is for commercially or privately insured patients. The *KRAS* Single Gene Test Program will provide a *KRAS* Mutation Analysis at no cost to any eligible patient, regardless of a patient's results and insurance. Patients will receive results from participating NeoGenomics Laboratories. Both programs are valid for testing performed through Dec. 31, 2021. To learn more about eligibility for these programs and read the full Terms and Conditions, visit www.BiomarkerAssist.com or contact 1-888-4ASSIST with questions.

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 collaborations, or potential collaborations, with any other company (including BeiGene, Ltd. or any collaboration to manufacture therapeutic antibodies against COVID-19), or the integration of Otezla® (apremilast) into our business (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, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, 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. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. 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, products or technology, and to integrate the operations of companies or to support the products or technology 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. Global economic conditions may magnify certain risks that affect our business. 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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