FDA Grants Sotorasib Priority Review Designation For The Treatment Of Patients With KRAS G12C-Mutated Locally Advanced Or Metastatic Non-Small Cell Lung Cancer

February 16, 2021

FDA Target Action Date is Aug. 16, 2021

THOUSAND OAKS, Calif., Feb. 16, 2021 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review for sotorasib for the treatment of patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), following at least one prior systemic therapy.

The FDA grants Priority Review to applications for medicines that offer significant improvements over available options by demonstrating safety or efficacy improvements, preventing serious conditions, or enhancing patient compliance. Based on the Priority Review designation, the Prescription Drug User Fee Action (PDUFA) date for sotorasib is Aug. 16, 2021, which is four months earlier than the standard review cycle.

The New Drug Application (NDA) is based on the Phase 2 results from the CodeBreaK 100 clinical trial that studied patients with locally advanced or metastatic NSCLC whose cancer had progressed despite treatment with chemotherapy and/or immunotherapy. Full results from the study were recently presented during the Presidential Symposium at the International Association for the Study of Lung Cancer (IASLC) 2020 World Conference on Lung Cancer (WCLC).

Amgen submitted the sotorasib NDA on Dec. 16, 2020. The NDA is being reviewed by the FDA under its Real-Time Oncology Review (RTOR), a pilot program that aims to explore a more efficient review process that ensures safe and effective treatments are made available to patients as early as possible. Amgen submitted a Marketing Authorization Application (MAA) in the EU in Dec. 2020. Additionally, Amgen submitted MAAs for sotorasib in Australia, Brazil, Canada and the United Kingdom in Jan. 2021 to participate in the FDA's Project Orbis initiative. Sotorasib has achieved Breakthrough Therapy Designation in the U.S. and China.

About Sotorasib

Amgen has taken on one of the toughest challenges of the last 40 years in cancer research by developing sotorasib, a $KRAS^{G12C}$ inhibitor.[1] Sotorasib was the first $KRAS^{G12C}$ inhibitor to enter the clinic and is being studied in the broadest global clinical program exploring 10 combinations with clinical sites spanning five continents. In just over two years, the sotorasib clinical program has established the deepest clinical data set with more than 700 patients studied across 13 tumor types.

About Non-Small Cell Lung Cancer and the KRAS G12C Mutation

NSCLC accounts for 80%-85% of all lung cancers, and most patients (66%) have advanced or metastatic disease at initial diagnosis.[2,3] *KRAS G12C* is one of the most common driver mutations in NSCLC and there is a high unmet need and poor outcomes associated in the second-line treatment of *KRAS G12C* driven NSCLC.[4] In the U.S., approximately 25,000 new patients are diagnosed with *KRAS G12C*-mutated NSCLC each year.[5]

About CodeBreaK

The CodeBreaK clinical development program for Amgen's investigational drug sotorasib is designed to treat patients with an advanced solid tumor with the *KRAS G12C* mutation and address the longstanding unmet medical need for these cancers.

CodeBreaK 100, the Phase 2, first-in-human, open-label multicenter study, enrolled patients with *KRAS G12C*-mutant solid tumors. Eligible patients must have received a prior line of systemic anticancer therapy, consistent with their tumor type and stage of disease. The primary endpoint for the Phase 2 study was centrally assessed objective response rate. The Phase 2 trial in NSCLC enrolled 126 patients, 124 of whom had centrally evaluable lesions by RECIST at baseline. The Phase 2 trial in colorectal cancer (CRC) is fully enrolled and topline results are expected in 2021.

A global Phase 3 randomized active-controlled study comparing sotorasib to docetaxel (CodeBreaK 200) is currently recruiting patients with *KRAS G12C*-mutant NSCLC. Amgen also has more than 10 Phase 1b combination studies across various advanced solid tumors (CodeBreaK 101) open for enrollment.

For information, please visit www.codebreaktrials.com.

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.

To learn more about Amgen's innovative pipeline with diverse modalities and genetically validated targets, please visit AmgenOncology.com. 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 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, 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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