Clinical Data From Full Phase 1 Cohort Of Investigational Sotorasib Published In New England Journal Of Medicine

September 20, 2020

Confirmed and Durable Anticancer Activity in Heavily Pretreated Non-Small Cell Lung Cancer (NSCLC) Patients From Phase 1 Trial

NSCLC Data Featured in Proffered Presentation Session at Virtual ESMO 2020

Manuscript Represents First Phase 1 Results Published for a KRAS G12C Inhibitor

THOUSAND OAKS, Calif., Sept. 20, 2020 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that updated data from the full Phase 1 cohort of the CodeBreaK 100 clinical study, evaluating sotorasib (proposed INN for AMG 510) in 129 patients across multiple advanced solid tumors, were published in the *New England Journal of Medicine* (NEJM). Data from 59 patients with advanced non-small cell lung cancer reported in the NEJM manuscript were also featured today during an oral presentation at ESMO 2020.

"CodeBreaK 100 is the largest Phase 1/2, and first-in-human, clinical study for a $KRAS^{G12C}$ inhibitor," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Earlier this year at ASCO, we reported encouraging early data in patients with advanced colorectal cancer and a number of other solid tumors. We're pleased to share these updated Phase 1 results, particularly in patients with advanced non-small cell lung cancer, and look forward to the Phase 2 readout in this heavily pretreated population later this year."

Sotorasib demonstrated confirmed objective response rate (ORR) and disease control rates (DCR) of 35.3% and 91.2%, respectively, in 34 heavily pretreated patients (median of two prior lines of therapy) with NSCLC, who were treated with the 960 mg daily dose (data cutoff of June 1, 2020).

Anticancer activity was seen across all dose levels in patients with NSCLC, with a confirmed ORR of 32.2% and DCR of 88.1%, and median duration of response of 10.9 months, with 10 of 19 responders still in response as of the data cutoff. Tumor shrinkage was observed in 71.2% of patients at the first week-6 assessment. Median progression-free survival (mPFS) in patients treated with sotorasib was 6.3 months.

Safety and tolerability in patients with NSCLC were consistent with previously seen CodeBreaK 100 results. No dose-limiting toxicities were observed and there were no fatal treatment-related adverse events (TRAEs). The most common TRAEs were diarrhea (25.4%), alanine aminotransferase (ALT) increase (20.3%), aspartate aminotransferase (AST) increase (20.3%), fatigue (10.2%) and nausea (10.2%). Eleven (18.6%) patients had grade 3 or higher TRAEs, one of whom had grade 3 TRAEs of ALT and AST increases that led to discontinuation of treatment.

"These latest results show that sotorasib continues to demonstrate encouraging clinical benefit in heavily pretreated patients with *KRAS G12C*-mutant tumors," said lead author David S. Hong, M.D., Department of Investigational Cancer Therapeutics, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, TX. "The results also establish a compelling trend in tumor shrinkage and median progression-free survival with a positive benefit-risk profile."

The ESMO oral presentation included Phase 1 NSCLC results published in *NEJM*, as well as data on potential biomarkers of response to sotorasib that demonstrated clinical activity across a range of *KRAS G12C* mutant allele frequencies (MAFs), PD-L1 tissues expression levels, tumor mutational burden (TMB) plasma levels and tissue co-mutational profiles.

"*KRAS G12C* is a driver of multiple solid tumor types and is particularly prevalent in non-small cell lung cancer," said Fabrice Barlesi, M.D., Ph.D., Professor of Medicine at Aix-Marseille University, Medical Director of Gustave Roussy Institute, Paris, France. "Despite this, there are currently no approved targeted therapy options for *KRAS G12C* and patients remain in need of additional treatment options, which makes these new findings particularly important."

Amgen Webcast Investor Call

Amgen will host two webcast calls for the investment community in conjunction with the ESMO Virtual Congress 2020. On Sunday, Sept. 20, 2020, at 11:00 a.m. PDT, David M. Reese, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team and clinical investigators, will discuss Phase 1 data being presented on the Company's investigational $KRAS^{G12C}$ inhibitor sotorasib (AMG 510). On Monday, Sept. 21, at 1:00 p.m. PDT, David M. Reese, M.D., along with members of Amgen's clinical development team, will discuss the Phase 1 data being presented on the Company's investigational half-life extended bispecific T-cell engager (BiTE®) immuno-oncology therapy targeting prostate-specific membrane antigen (PSMA).

Live audio of the conference call will be broadcast over the internet simultaneously and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given at certain investor and medical conferences, can be accessed on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

About *KRAS*

The *RAS* gene family, which has been the subject of almost four decades of research, contains some of the most frequently mutated oncogenes in human cancers.[1,2] Targeting the KRAS protein, the most commonly altered family member in solid tumors, has been one of the toughest challenges in cancer research.[1] A specific mutation known as *KRAS G12C*, is a major driver of tumor growth, occurring broadly across solid tumor indications. In the U.S., about 13% of patients with non-small cell lung cancer harbor the *KRAS G12C* mutation.[3,4] It is also found in approximately 3-5% of colorectal

cancers and 1-2% of numerous other solid tumors, making this among the most broadly represented mutations across cancer patient subgroups.[5,6,7,8,9]. With the discovery of a unique surface groove in the $KRAS^{G12C}$ protein, Amgen developed and advanced the first investigational $KRAS^{G12C}$ inhibitor into the clinic and is exploring the potential of $KRAS^{G12C}$ inhibition across multiple tumor types for patients who remain in dire need of treatment options.[1,10]

About CodeBreaK
The CodeBreaK clinical trial 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 1 and 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 1 study is safety, and key secondary endpoints include objective response rate (assessed every six weeks), duration of response and progression-free survival. Patients were enrolled in four dose cohorts: 180 mg, 360 mg, 720 mg and 960 mg, taken orally once a day.

Amgen's single-arm Phase 2 trials in both non-small cell lung cancer (NSCLC) and colorectal cancer (CRC) (also part of CodeBreaK 100) are now fully enrolled. The potentially registrational Phase 2 trial in NSCLC is on track for data readout later in 2020 and a global Phase 3 randomized active-controlled confirmatory study comparing sotorasib to docetaxel in NSCLC (CodeBreaK 200) has begun recruiting. The Phase 2 CRC trial is expected to have a data readout in 2021. Amgen is also currently enrolling six Phase 1b combination studies across various advanced solid tumors (CodeBreaK 101).

Additional information about CodeBreaK clinical trials can be found at http://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 or potential collaboration in pursuit of therapeutic antibodies against COVID-19 (including statements regarding such collaboration's, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 or antibodies against targets other than the SARS-CoV-2 receptor binding domain, and/or to produce any such antibodies to potentially prevent or treat 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. 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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