Amgen's Investigational KRAS G12C Inhibitor Sotorasib Demonstrated Rapid, Deep And Durable Responses In Previously Treated Patients With Advanced Non-Small Cell Lung Cancer

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37.1% of Patients Responded to Sotorasib Treatment, With a Median Duration of Response of 10 Months
Median Tumor Shrinkage Among all Responders was 60% and Complete Responses Observed
Sotorasib is First KRAS G12C Inhibitor to Show Progression-Free Survival (6.8 months)

THOUSAND OAKS, Calif., Jan. 28, 2021 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced results from the Phase 2 cohort of the CodeBreaK 100 clinical study evaluating investigational sotorasib (AMG 510) in 126 patients with *KRAS G12C*-mutated advanced non-small cell lung cancer (NSCLC). The results will be presented during the Presidential Symposium at the International Association for the Study of Lung Cancer (IASLC) 2020 World Conference on Lung Cancer (WCLC) and are the first from a completed pivotal Phase 2 study in NSCLC with a median follow-up of more than one year.

Sotorasib demonstrated a confirmed objective response rate (ORR) and disease control rate (DCR) of 37.1% and 80.6%, respectively, and a median duration of response of 10 months (data cutoff of Dec.1, 2020; median follow-up time was 12.2 months). The results also highlighted that sotorasib is the first $KRAS^{G12C}$ inhibitor to show progression-free survival (median of 6.8 months) in a Phase 2 study, which is consistent with earlier Phase 1 results in previously treated patients with *KRAS G12C*-mutated advanced NSCLC.

Patients were treated with sotorasib 960 mg once daily orally. Prior to the trial, 81% of patients had progressed on both platinum-based chemotherapy and PD1/L1 inhibitors, with the remainder progressing after having received one of these therapies.

"Patients with advanced non-small cell lung cancer who have failed first-line treatment face extremely poor outcomes with limited treatment options available to them, and Amgen has been committed to changing that," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Targeting KRAS has been a 40-year quest by scientists and researchers around the world, and we are extremely pleased that sotorasib has successfully demonstrated rapid, deep and durable responses in this registrational Phase 2 study that was conducted in record time. We are proud that sotorasib may potentially become the first approved targeted therapy for these patients."

Over 80% of patients achieved disease control, including three complete responses and 43 partial responses, and the median best tumor shrinkage among all responders (n=46) was 60%. The median time to objective response was 1.4 months. Sotorasib had a favorable benefit-risk profile with most treatment-related adverse events (TRAEs) mild-to-moderate (grade 1 or 2) and no treatment-related deaths. Grade 3 TRAEs were reported in 25 (19.8%) patients and only one patient (0.8%) reported a Grade 4 TRAE. The most frequently reported TRAEs (any grade) were diarrhea (31.0%), nausea (19.0%), increased alanine aminotransferase (15.1%) and increased aspartate aminotransferase (15.1%). TRAEs led to treatment discontinuation in only 7.1% of patients.

"These results are encouraging and clinically meaningful for patients with advanced NSCLC harboring the *KRAS G12C* mutation," said Bob T. Li, MD, PhD, MPH, medical oncologist and principal investigator at Memorial Sloan Kettering Cancer Center. "These are patients who have progressive disease after standard treatment, so they need additional treatments, and the fact that we are seeing rapid tumor shrinkages and durable responses in these patients, is for me a step forward and a win for patients."

In exploratory analyses, encouraging tumor response to sotorasib was observed across a range of biomarker subgroups, including patients with negative or low PD-L1 expression level and those with STK11 mutation. This co-mutation has been associated with poor outcomes in NSCLC patients treated with checkpoint inhibitors and chemotherapy.

"Despite recent treatment advances, survival outcomes remain poor for patients with advanced stage non-small cell lung cancer on second and third-line therapies with the *KRAS G12C* mutation. Currently there are no targeted treatment options for them, and I am excited about the advances that Amgen is pioneering in this field to potentially help improve patient outcomes," said Dr. Upal Basu Roy, vice president of Research, LUNGevity.

Following recent regulatory submissions in the U.S., European Union, Australia, Brazil, Canada and UK, Amgen is working with regulatory agencies across the globe to bring sotorasib to NSCLC patients as quickly as possible. Sotorasib has achieved Breakthrough Therapy Designation in the U.S.

NSCLC accounts for 80%-85% of all lung cancers, and most patients (66%) have advanced or metastatic disease at initial diagnosis.[1,2] *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.[3] In the U.S., about 13% of patients with NSCLC harbor the *KRAS G12C* mutation,[4,5] and each year approximately 25,000 new patients in the U.S. are diagnosed with *KRAS G12C*-mutated NSCLC.[6]

Amgen Webcast Investor Call
Amgen will host a webcast call for the investment community in conjunction with WCLC 2020. On Friday, Jan. 29, 2021, at 5 p.m. PST, 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 registrational Phase 2 NSCLC data being presented on the Company's investigational $KRAS^{G12C}$ inhibitor sotorasib.

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.

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

About Sotorasib

Amgen has taken on one of the toughest challenges of the last 40 years in cancer research by developing sotorasib, an investigational $KRAS^{G12C}$ inhibitor.[7] Sotorasib was the first $KRAS^{G12C}$ inhibitor to enter the clinic and is being studied in the broadest clinical program exploring 10 combinations with global sites spanning five continents. In just over two years, the sotorasib clinical program has established the largest clinical data set with more than 700 patients studied across 13 tumor types to date.

Sotorasib has demonstrated a positive benefit-risk profile with fast, deep and durable anticancer activity in patients with NSCLC harboring the *KRAS G12C* mutation with a once daily oral formulation. Promising responses have also been observed in multiple other solid tumors.[8]

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 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 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 in patients with *KRAS G12C*-mutated NSCLC (CodeBreaK 200) is currently recruiting. 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.

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. 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.

CONTACT: Amgen, Thousand Oaks
Trish Rowland, 805-447-5631 (Media)
Jessica Akopyan, 805-447-0974 (media)
Arvind Sood, 805-447-1060 (Investors)

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