Amgen Presents New AMG 510 Clinical Data Across Multiple Solid Tumors During ASCO20 Virtual Scientific Program

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Data in Advanced Colorectal Cancer Show Disease Control Rate of 80% at Target Dose
Anti-Tumor Activity Observed Across Multiple Solid Tumors
CodeBreaK is the Most Extensive KRAS G12C Clinical Development Program

THOUSAND OAKS, Calif., May 29, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced new data from the CodeBreaK 100 clinical development program evaluating investigational AMG 510 (proposed INN sotorasib) in heavily pretreated patients with a range of *KRAS G12C*-mutant solid tumors. Updated Phase 1 data from patients with advanced colorectal cancer (CRC) and other selected solid tumors continued to demonstrate disease control activity, safety and tolerability. These data are being presented during the ASCO20 Virtual Scientific Program, May 29 – 31, 2020.

"Targeting *KRAS* has been a 40-year quest leaving patients with limited treatment options. In just under two years in the clinic, we have seen encouraging early efficacy and safety data across a number of solid tumors," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "New Phase 1 data at ASCO show that, in some patients with advanced colorectal cancer, sotorasib monotherapy provided prolonged disease control. A Phase 2 monotherapy study in advanced colorectal cancer has fully enrolled and will provide further insights into the potential utility of sotorasib in this disease."

Sotorasib Activity in Patients With Advanced Colorectal Cancer
CRC is the second leading cause of cancer deaths worldwide.[1] It is the third most commonly diagnosed cancer globally and incidence is expected to grow by more than 20% over the next decade.[2] For patients with previously treated metastatic CRC receiving standard therapies, unmet need remains high, with median progression-free survival (PFS) of about 2 months and response rates of less than 2%.[3,4]

This Phase 1 dose escalation study evaluated 42 heavily pretreated patients with advanced *KRAS G12C*-mutant CRC (data cut-off of Jan. 2020). All patients received prior systemic therapies (median of three prior lines), with 69% having received three or more prior lines of therapy. Twenty-two (52.4%) and eight (19.0%) patients remained on treatment for more than three and six months, respectively.

In the 960 mg once-daily target dose cohort, the objective response rate (ORR) was 12% (3/25) and the disease control rate (DCR) was 80% (20/25). Median PFS was 4.2 months and overall survival (OS) had not been reached after a median follow-up of almost 8 months. Tumor shrinkage was observed in 11 of 23 patients with available post-baseline tumor data.

Across all dose levels, the majority of patients achieved disease control, with an ORR of 7.1% and a DCR of 76.2%. Disease stability was maintained for a median of 4.2 months. Median PFS was 4.0 months and median OS was 10.1 months. Tumor shrinkage was observed in 18 of 39 patients with available post-baseline tumor data across all doses.

"There is currently a tremendous treatment gap for patients with advanced *KRAS G12C*-mutant colorectal cancer," said Marwan G. Fakih, M.D., primary study investigator and co-director of the Gastrointestinal Cancer Program, City of Hope, Duarte, California. "These latest sotorasib data continue to show encouraging antitumor activity and tolerability in a patient population that has few treatment options."

Disease progression was the most common reason for treatment discontinuation. The majority of treatment-related adverse events (TRAEs) were Grade 1 and 2. Only two TRAEs were Grade 3 (diarrhea and anemia). There were no Grade 4 or higher TRAEs.

Sotorasib Activity in Patients With Advanced Solid Tumors Other Than NSCLC or CRC
Data were evaluated for 25 heavily pretreated patients with advanced *KRAS G12C*-mutant solid tumors other than CRC or NSCLC. These patients had received a median three prior lines of therapy with a median follow-up of 4.3 months.

These data demonstrated early evidence of a consistent safety profile and anticancer activity across a range of advanced *KRAS G12C*-mutant solid tumors, including pancreatic, appendiceal and endometrial cancer. Partial responses were confirmed in three patients with appendiceal, melanoma and endometrial cancer, respectively. Six of eight evaluable patients with pancreatic cancer achieved stable disease, and three had approximately a 30% reduction in tumor burden from baseline. Tumor shrinkage was observed in 13 of 19 evaluable patients with available post-baseline tumor data across all tumor types.

A complete listing of Amgen posters is available on the ASCO website at www.asco.org.

About *KRAS*
The subject of almost four decades of research, the *RAS* gene family contains the most frequently mutated oncogenes in human cancers.[5,6] Within this family, *KRAS* is the most prevalent variant and is particularly common in solid tumors.[5] A specific mutation known as *KRAS G12C* is found in approximately 13% of non-small cell lung cancers, 3% to 5% of colorectal cancers and 1% to 2% of numerous other solid tumors.[7-9] The $KRAS^{G12C}$ protein has been considered "undruggable" due to a lack of traditional small molecule binding pockets on the protein. Amgen is exploring the potential of $KRAS^{G12C}$ inhibition across a broad variety of solid tumor types.

About CodeBreaK
The CodeBreaK clinical trial program for Amgen's investigational drug sotorasib is designed to treat patients with multiple *KRAS G12C*-mutant solid tumors 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 were heavily pretreated with at least two or more prior lines of treatment, 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 in 2020. The Phase 2 CRC trial is expected to have a data readout in early 2021.

Amgen is currently enrolling six Phase 1b combination studies across various advanced solid tumors (CodeBreaK 101). In addition, a randomized global Phase 3 confirmatory study in NSCLC (CodeBreaK 200) has been initiated. 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.

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 Adaptive Biotechnologies (including statements regarding such collaboration's ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 to potentially prevent or treat COVID-19), 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, 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.

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