# Amgen To Showcase Data From Oncology Pipeline During ESMO Virtual Congress 2020

September 16, 2020

**Sotorasib Phase 1 Non-Small Cell Lung Cancer Data From the CodeBreaK 100 Clinical Study**

**First Clinical Data Disclosure for Investigational AMG 160, a Half-Life Extended PSMA-Targeted BiTE® Molecule**

THOUSAND OAKS, Calif., Sept. 16, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) announced today that data from its oncology pipeline in solid tumors will be presented during the European Society of Medical Oncology (ESMO) Virtual Congress 2020, Sept. 19-21, 2020.

Amgen will present new data for AMG 510 (proposed INN: sotorasib) and AMG 160 during two oral presentations. Data from the study of sotorasib, Amgen's investigational $KRAS^{G12C}$ inhibitor, will showcase Phase 1 clinical results on durability of clinical benefit in patients with non-small cell lung cancer (NSCLC). Additionally, data from Amgen's bispecific T cell engager (BiTE®) platform will feature preliminary safety and efficacy findings from the ongoing Phase 1 study of AMG 160, an investigational half-life extended BiTE immuno-oncology therapy targeting prostate-specific membrane antigen (PSMA). Abstracts will be released on Saturday, Sept. 19, and will be followed by oral presentations (sotorasib, Sunday Sept. 20 and AMG 160, Monday Sept. 21) that will highlight more recent data.

"During ESMO, we will highlight our pioneering work in two key areas of oncology research – *KRAS* inhibition and BiTE therapies," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Clinicians will be presenting updated data from the first and largest Phase 1 human clinical study of an investigational $KRAS^{G12C}$ inhibitor, sotorasib -- now the first $KRAS^{G12C}$ inhibitor to advance to a Phase 3 study. In addition, early and encouraging data from our BiTE platform in the solid tumor setting will be presented. Our data at ESMO underscore our unique approach to harnessing the human biology of cancer to alter the course of cancer care for patients who need it most."

Learn more about Amgen's development of innovative medicines for novel targets in difficult-to-treat solid tumors at AmgenOncology.com.

***Key Clinical Abstracts and Presentation Times (Pipeline):***

- **Durability of Clinical Benefit and Biomarkers in Patients (pts) With Advanced Non-Small Cell Lung Cancer (NSCLC) Treated With AMG 510 (sotorasib)***
  Presentation #1257O, Proffered Paper Session, Sunday, Sept. 20, 2020, from 2:25 p.m. – 2:37 p.m. CEST / 5:25 a.m. – 5:37 a.m. PDT
- **Results From a Phase 1 Study of AMG 160, a Half-Life Extended (HLE), PSMA-Targeted, Bispecific T Cell Engager (BiTE®) Immune Therapy for Metastatic Castration-Resistant Prostate Cancer (mCRPC)**
  Presentation #609O, Proffered Paper Session, Monday, Sept. 21, 2020, from 2:25 p.m. – 2:37 p.m. CEST / 5:25 a.m. – 5:37 a.m. PDT

**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.

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

**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 later in 2020 and a Phase 3 trial comparing sotorasib with docetaxel in NSCLC has begun recruiting. 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 BiTE® Technology**

BiTE® (bispecific T cell engager) technology is a targeted immuno-oncology platform that is designed to engage patient's own T cells to any tumor-specific antigen, activating the cytotoxic potential of T cells to eliminate detectable cancer. The BiTE immuno-oncology platform has the potential to treat different tumor types through tumor-specific antigens. The BiTE platform has a goal of leading to off-the-shelf solutions, which have the potential to make innovative T cell treatment available to all providers when their patients need it. Amgen is advancing more than a dozen BiTE molecules across a broad range of hematologic malignancies and solid tumors, further investigating BiTE technology with the goal of enhancing patient experience and therapeutic potential. To learn more about BiTE technology, visit www.AmgenBiTETechnology.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, 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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