Amgen Announces New Clinical Data Evaluating Novel Investigational KRAS(G12C) Inhibitor In Larger Patient Group At WCLC 2019

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54% of 13 Evaluable Non-Small Cell Lung Cancer Patients Experienced a Partial Response at the Target Dose of 960 mg in the Ongoing Phase 1 Study

46% of Patients had Stable Disease for a Disease Control Rate of 100% at the Target Dose

FDA Grants AMG 510 Fast Track Designation for Previously Treated Metastatic NSCLC With KRAS G12C Mutation

THOUSAND OAKS, Calif., Sept. 8, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced new data from the ongoing Phase 1 study evaluating AMG 510 in patients with previously treated *KRAS G12C*-mutated solid tumors. AMG 510 is a first-in-class investigational oral therapy that is designed to selectively and irreversibly target the $KRAS^{G12C}$ protein. The additional follow-up in a larger group of patients with non-small cell lung cancer (NSCLC) continued to show anti-tumor activity with no dose-limiting toxicities. These data are being presented during an oral presentation at IASLC 2019 World Conference on Lung Cancer (WCLC) hosted by the International Association for the Study of Lung Cancer.

Initial data from the Phase 1 study were presented at the 55^{th} Annual Meeting of the American Society of Clinical Oncology (ASCO) earlier this year. The additional follow-up in a larger group of patients being presented at WCLC includes a subset of 34 NSCLC patients enrolled, with 23 of the patients being evaluable for efficacy. Thirteen of the evaluable patients received the target dose of 960 mg once daily, of which seven (54%) achieved a partial response at one or more timepoints and six (46%) achieved stable disease, for a disease control rate of 100%.

"These new data reinforce the earlier positive response rate we shared at ASCO in more non-small cell lung cancer patients receiving AMG 510," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We remain enthusiastic about the promise of AMG 510 and continue to rapidly advance its development program both as monotherapy and in combination."

Among the 34 NSCLC patients enrolled, there were no observed dose-limiting toxicities and no adverse events leading to discontinuation. Twenty-seven of these patients remain on treatment. Of the 34 patients, only nine (26.5%) reported treatment-related adverse events (TRAEs) of grade 1 or 2. Three patients reported grade 3 TRAEs (anemia and diarrhea). There were no grade 4 or higher TRAEs.

"There is a need for targeted treatments for specific driver mutations of cancer that do not have an approved therapy," said Ramaswamy Govindan, M.D., principal investigator and professor at Washington University School of Medicine in St. Louis. "These data continue to show encouraging anti-tumor activity with AMG 510, underscoring the potential to close the treatment gap for non-small cell lung cancer patients with previously treated *KRAS G12C*-mutated NSCLC."

Additional data on AMG 510 will be presented at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain from Sept. 27-Oct. 1.

About the Phase 1 Study

The Phase 1, 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 is safety, and key secondary endpoints include pharmacokinetics, 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.

About *KRAS*

The subject of more than three decades of research, the *RAS* gene family are the most frequently mutated oncogenes in human cancers.[1,2] Within this family, *KRAS* is the most prevalent variant and is particularly common in solid tumors.[2] A specific mutation known as *KRAS G12C* accounts for approximately 13% of non-small cell lung cancers, 3-5% of colorectal cancers and one to two percent of numerous other solid tumors.[3] Approximately 30,000 patients are diagnosed each year in the United States with *KRAS G12C*-driven cancers.[4] $KRAS^{G12C}$ 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 tumor types.

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 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 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. 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 acquire other companies or products and to integrate the operations of companies 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 relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the European Medicines Agency 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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