AMGEN DATA AT WCLC 2022 HIGHLIGHTS POTENTIAL TO DELIVER TRANSFORMATIVE MEDICINES FOR HISTORICALLY DIFFICULT-TO-TREAT LUNG CANCERS

August 7, 2022

First Data From LUMAKRAS Plus Immunotherapy and LUMAKRAS Plus SHP2 Inhibitor Combinations Show Clinical Activity and Support Ongoing Investigation

Updated Phase 1 Tarlatamab Data Reinforce Potential of BiTE® Therapy in Small Cell Lung Cancer

THOUSAND OAKS, Calif., Aug. 7, 2022 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced three new data sets from its thoracic oncology portfolio that will be presented at the International Association for the Study of Lung Cancer (IASLC) 2022 World Conference on Lung Cancer (WCLC) from August 6-9 in Vienna, Austria. The data presented will include new combination study results: LUMAKRAS® (sotorasib) with pembrolizumab or atezolizumab and LUMAKRAS with RMC-4630, a small molecule protein tyrosine phosphatase 2 (SHP2) inhibitor. In addition, new data will be featured from the DeLLphi300 clinical trial, a Phase 1 dose exploration and expansion study evaluating the safety and efficacy of tarlatamab, a first-in-class half-life extended bispecific T-cell engager (HLE BiTE®) molecule targeting delta-like ligand 3 (DLL3), in small cell lung cancer (SCLC).

"Amgen is working to deliver the next frontier of treatment in lung cancer to help change patient outcomes in these historically difficult-to-treat cancers, and we're pleased to present LUMAKRAS data for non-small cell lung cancer and tarlatamab data for small cell lung cancer, a disease where there are no therapies specifically approved to treat patients in the third-line setting," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "As part of the LUMAKRAS comprehensive clinical trial program we are exploring multiple approaches to front-line treatment, including the initiation of a Phase 3 study combining LUMAKRAS with chemotherapy for patients with PD-L1-negative tumors and moving forward with the Phase 1 dose expansion of LUMAKRAS in combination with checkpoint inhibitors. We are also advancing novel approaches like the SHP2 inhibitor combination trials."

LUMAKRAS in Combination with Pembrolizumab or Atezolizumab (Abstract OA03.06)
In a Phase 1b CodeBreaK 100/101 dose exploration study, a total of 58 $KRAS^{G12C}$ inhibitor-naïve patients with *KRAS* G12C-mutated non-small cell lung cancer (NSCLC) were treated across 12 cohorts at varying doses of LUMAKRAS (120–960 mg daily) in combination with intravenous atezolizumab (1200 mg) or pembrolizumab (200 mg) administered concurrently every three weeks until intolerability or disease progression. Half of the cohorts were lead-in, where patients received LUMAKRAS monotherapy for either 21 or 42 days before their first combination dose. The majority of patients (67%) received prior immunotherapy and the median follow-up time was 12.8 months.

In this mostly pre-treated NSCLC population, combining LUMAKRAS with immunotherapy showed an objective response rate (ORR) of 29% (17/58 patients across all cohorts). Among the 17 confirmed responders, five patients had an observed duration of response (DoR) greater than 10 months, with eight ongoing responders. The combination of LUMAKRAS with immunotherapy also led to a higher incidence of grade 3-4 treatment-related adverse events (TRAEs) than previously observed with LUMAKRAS monotherapy, primarily liver enzyme elevations. However, lead-in cohorts demonstrated durable clinical activity with lower rates of discontinuation and grade 3-4 TRAEs compared to concurrent cohorts. Nearly all grade 3-4 TRAEs occurred outside of the 21-day dose limiting toxicity window and were resolved. Dose expansion is ongoing in treatment-naïve patients using LUMAKRAS lead-in followed by combination of LUMAKRAS with pembrolizumab.

"For the first time, we demonstrated that sotorasib in combination with an immune checkpoint inhibitor such as pembrolizumab or atezolizumab produced durable responses in both pre-treated immunotherapy and in naive settings," said Bob T. Li, MD, PhD, MPH, medical oncologist and principal investigator at Memorial Sloan Kettering Cancer Center who is the study's presenting author. "Insights from this CodeBreaK research show us that while hepatotoxicity events did occur, they tended to appear after the second or third cycle of immunotherapy administration, but all were resolved with appropriate clinical measures. The fact that we saw a median duration of response of 17.9 months and lower rates of adverse events in patients treated with sotorasib as a lead-in to the combination regimen informs our approach for ongoing investigation in the first-line setting."

LUMAKRAS in Combination with RMC-4630 (Abstract OA03.03)
In a separate dose exploration of the CodeBreaK 101 Phase 1b master study, a total of 27 patients with *KRAS* G12C-mutated tumors, including 11 patients with NSCLC, were treated with LUMAKRAS and escalating dose levels of RMC-4630. Patients had received a median of three prior lines of therapy, with 41% having prior $KRAS^{G12C}$ inhibitor therapy.

"As with all of the CodeBreaK sotorasib combination arms, preclinical and biomarker rationale informed the evaluation of sotorasib with RMC-4630, as genomic alterations of receptor tyrosine kinase (RTK) were identified as a common resistance mechanism to sotorasib, highlighting the potential role for combining sotorasib with upstream RTK signaling inhibitors," said Gerald S. Falchook, M.D., principal investigator and director of drug development, Sarah Cannon Research Institute at HealthONE. "These first safety and efficacy data support further investigation to expand treatment options for patients with the *KRAS* G12C mutation."

The data demonstrated promising clinical activity in patients with *KRAS* G12C-mutated NSCLC treated with the LUMAKRAS and RMC-4630 combination, most notably in $KRAS^{G12C}$ inhibitor-naïve patients. Of the 11 NSCLC patients enrolled, three patients (27%) achieved a confirmed partial response (PR) with two responses ongoing at the time of data cut-off, and seven patients (64%) achieved disease control. For the six $KRAS^{G12C}$ inhibitor-naïve patients, an ORR of 50% was observed and all patients demonstrated disease control. Overall, TRAEs occurred in 63% of patients, the most common were edema (30%) and diarrhea (26%). The LUMAKRAS and RMC-4630 combination dose escalation was completed with grade 3 TRAEs occurring in 22% of patients and without any grade 4 and higher TRAEs.

Dose expansion is underway in both $KRAS^{G12C}$ inhibitor-naïve and $KRAS^{G12C}$ inhibitor-exposed NSCLC patients.

Advancing Tarlatamab (AMG 757) in Small Cell Lung Cancer (SCLC) (Abstract OA12.05)
Updated data from the DeLLphi300 clinical trial evaluating tarlatamab in SCLC will be presented during the Novel and Combination Strategies for

SCLC oral session (OA12) on Monday, August 8, 2022.

"There remains an urgent need for additional treatment options for patients with small cell lung cancer, an aggressive form of lung cancer associated with poor prognosis and where there are no therapies specifically approved for third-line treatment," said Hossein Borghaei, DO, MS, chief of the Division of Thoracic Medical Oncology at Fox Chase Cancer Center. "Data that will be presented at WCLC show that tarlatamab has the potential to offer a new approach – binding a novel tumor antigen expressed on a majority of SCLC tumor cells, DLL3, while engaging T cells directly at the site of the tumor microenvironment to activate a better response."

Based on the latest data, a potentially registrational Phase 2 study of tarlatamab in the third-line treatment of SCLC is enrolling patients. Additional studies investigating tarlatamab are underway, including DeLLphi-303, a Phase 1b study testing tarlatamab in combination with standard of care in first-line SCLC and a Phase 1b study in de novo or treatment-emergent neuroendocrine prostate cancer.

Amgen to Webcast Investor Meeting at WCLC 2022

Amgen (NASDAQ: AMGN) will host a webcast call for the investment community in conjunction with the International Association for the Study of Lung Cancer (IASLC) 2022 World Conference on Lung Cancer (WCLC) at 12:00 p.m. ET on Monday, Aug. 8, 2022. David M. Reese, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team, will discuss the data being presented on LUMAKRAS® (sotorasib) in combination with immunotherapy and in combination with a SHP2 inhibitor in non-small cell lung cancer, as well as tarlatamab data in small cell lung cancer.

The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found 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 LUMAKRAS®/LUMYKRAS® (sotorasib)

Amgen took on one of the toughest challenges of the last 40 years in cancer research by developing LUMAKRAS/LUMYKRAS, a $KRAS^{G12C}$ inhibitor.[1] LUMAKRAS/LUMYKRAS has demonstrated a positive benefit-risk profile with rapid, deep, and durable anticancer activity in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring the *KRAS* G12C mutation with a once daily oral formulation.[2]

Amgen is progressing the largest and broadest global $KRAS^{G12C}$ inhibitor development program with unparalleled speed and exploring more than 10 sotorasib combination regimens, including triplets, with clinical trial sites spanning five continents. To date, over 6,500 patients around the world have received LUMAKRAS/LUMYKRAS through the clinical development program, expanded access and commercial use.

In May 2021, LUMAKRAS was the first $KRAS^{G12C}$inhibitor to receive regulatory approval with its approval in the U.S., under accelerated approval. In total, LUMAKRAS/LUMYKRAS is approved in over 44 markets around the world, including the European Union, Japan, United Arab Emirates, South Korea, Hong Kong, Switzerland, Taiwan and Qatar, and in Australia, Brazil, Canada, Great Britain, Israel and Singapore under the U.S. FDA's Project Orbis. Amgen has submitted MAAs in Argentina, Colombia, Kuwait, Malaysia, Mexico, Saudi Arabia, Thailand and Turkey.

LUMAKRAS/LUMYKRAS is also being studied in multiple other solid tumors.[3]

About Non-Small Cell Lung Cancer and the *KRAS* G12C Mutation

Lung cancer is the leading cause of cancer-related deaths worldwide, and it accounts for more deaths worldwide than colon cancer, breast cancer and prostate cancer combined.[4] Overall survival rates for NSCLC are improving but remain poor for patients with advanced disease and 5-year survival is only 8% for those with metastatic disease.[5]

KRAS G12C is the most common *KRAS* mutation in NSCLC.[6] About 13% of patients with NSCLC harbor the *KRAS* G12C mutation.[7] Unmet medical need remains high and treatment options are limited for NSCLC patients with the *KRAS* G12C mutation whose first-line treatment has failed to work or has stopped working. The outcomes with other approved therapies are suboptimal, with a median progression-free survival of approximately four months following second-line treatment of *KRAS* G12C-mutated NSCLC.[8]

About CodeBreaK

The CodeBreaK clinical development program for Amgen's drug sotorasib is designed to study 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.[9] 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.[2] The Phase 2 trial in colorectal cancer (CRC) is fully enrolled and results have been published.[10]

CodeBreaK 200, the global Phase 3 randomized active-controlled study comparing sotorasib to docetaxel in *KRAS* G12C-mutated NSCLC completed enrollment of 345 patients. Eligible patients had previously treated, locally advanced and unresectable or metastatic *KRAS* G12C-mutated NSCLC. The primary endpoint is progression-free survival and key secondary endpoints include overall survival, objective response rate, and patient-reported outcomes.[11]

Amgen also has several Phase 1b studies investigating sotorasib monotherapy and sotorasib combination therapy across various advanced solid tumors (CodeBreaK 101) open for enrollment.[12] A Phase 2 randomized study will evaluate sotorasib in patients with stage IV *KRAS* G12C-mutated NSCLC in need of first-line treatment (CodeBreaK 201).[13]

For information, please visit www.hcp.codebreaktrials.com.

LUMAKRAS® (sotorasib) U.S. Indication

LUMAKRAS is indicated for the treatment of adult patients with *KRAS* G12C-mutated locally advanced or metastatic non-small cell lung cancer

(NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

LUMAKRAS® (sotorasib) Important U.S. Safety Information

Hepatotoxicity

- LUMAKRAS can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis.
- Among 357 patients who received LUMAKRAS in CodeBreaK 100, hepatotoxicity occurred in 1.7% (all grades) and 1.4% (Grade 3). A total of 18% of patients who received LUMAKRAS had increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST); 6% were Grade 3 and 0.6% were Grade 4. In addition to dose interruption or reduction, 5% of patients received corticosteroids for the treatment of hepatotoxicity.
- Monitor liver function tests (ALT, AST and total bilirubin) prior to the start of LUMAKRAS every 3 weeks for the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop transaminase and/or bilirubin elevations.
- Withhold, dose reduce or permanently discontinue LUMAKRAS based on severity of adverse reaction.

Interstitial Lung Disease (ILD)/Pneumonitis

- LUMAKRAS can cause ILD/pneumonitis that can be fatal. Among 357 patients who received LUMAKRAS in CodeBreaK 100, ILD/pneumonitis occurred in 0.8% of patients, all cases were Grade 3 or 4 at onset, and 1 case was fatal. LUMAKRAS was discontinued due to ILD/pneumonitis in 0.6% of patients.
- Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold LUMAKRAS in patients with suspected ILD/pneumonitis and permanently discontinue LUMAKRAS if no other potential causes of ILD/pneumonitis are identified.

Most Common Adverse Reactions

- The most common adverse reactions ≥ 20% were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity and cough.

Drug Interactions

- Advise patients to inform their healthcare provider of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, dietary and herbal products.
- Inform patients to avoid proton pump inhibitors and H_2 receptor antagonists while taking LUMAKRAS.
- If coadministration with an acid-reducing agent cannot be avoided, inform patients to take LUMAKRAS 4 hours before or 10 hours after a locally acting antacid.

Please see LUMAKRAS full Prescribing Information.

About Tarlatamab
Tarlatamab is an investigational first-in-class half-life extended bispecific T-cell engager (BiTE) molecule that is uniquely designed to target delta-like ligand 3 (DLL3) in neuroendocrine cancers, such as small cell lung cancer (SCLC) and neuroendocrine prostate cancer – both of which have high unmet medical needs.[14,15] DLL3 is highly upregulated on the cell surface of neuroendocrine tumors and rarely expressed on nonmalignant cells, making it a novel target for investigating a BiTE immuno-oncology molecule.[15,16,17]

Tarlatamab is being investigated in multiple studies, including DeLLphi-301, a potentially registrational Phase 2 study in relapsed/refractory SCLC; DeLLphi-303, a Phase 1b study testing tarlatamab in combination with standard of care therapies in first-line SCLC; DeLLphi-302, a Phase 1b combination study with AMG 404 in second-line or later SCLC; and DeLLpro-300, a Phase 1b study in de novo or treatment-emergent neuroendocrine prostate cancer.

About Small Cell Lung Cancer
Small cell lung cancer (SCLC) is a particularly aggressive form of the disease that accounts for about 10% to 15% of all lung cancers.[18] SCLC tends to spread faster than NSCLC, with nearly 70% of people with SCLC having metastatic disease at the time of diagnosis.[18]

The five-year survival rate for advanced SCLC remains low at 3% and unfortunately treatment options have not changed much in several decades.[5,19] Delta-like ligand 3 (DLL3) is an emerging treatment target that is expressed in greater than 80% of SCLC tumors with minimal expression in normal cells.[20]

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 a number of 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
At Amgen Oncology, our mission to serve patients drives all that we do. That's why we're relentlessly focused on accelerating the delivery of medicines that have the potential to empower all angles of care and transform lives of people with cancer.

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.

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.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2021, Amgen was named one of the 25 World's Best Workplaces™ by Fortune and Great Place to Work™ and one of the 100 most sustainable companies in the world by *Barron's*.

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., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, or the Teneobio, Inc. acquisition, or the recently announced proposed acquisition of ChemoCentryx, Inc., 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, 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 and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. 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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