AMGEN PRESENTS NEW TARLATAMAB DATA IN SMALL CELL LUNG CANCER

October 20, 2023

Tarlatamab Delivered an Encouraging Objective Response Rate of 40% and Median Overall Survival of 14.3 Months in Patients with Advanced SCLC

Late-Breaking Data Presented at ESMO and Published in the *New England Journal of Medicine* (NEJM)

Tarlatamab is an Investigational Delta-Like Ligand 3 (DLL3) Targeting BiTE® Molecule

THOUSAND OAKS, Calif., Oct. 20, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced results from the global Phase 2 DeLLphi-301 study, evaluating tarlatamab, an investigational delta-like ligand 3 (DLL3) targeting BiTE® (bispecific T-cell engager) molecule, in patients with advanced stage small cell lung cancer (SCLC) who had failed two or more prior lines of treatment. The data are being presented today at 3:20 PM CEST at a Proffered Paper session as a late-breaking oral presentation (LBA92) during the European Society for Medical Oncology (ESMO) Congress 2023 in Madrid, Spain, with publication in the *New England Journal of Medicine*.

With a median follow-up of 10.6 months, an intention-to-treat analysis that included 100 patients at the selected 10 mg dose for tarlatamab demonstrated an objective response rate (ORR; primary endpoint) of 40% (97.5% Confidence Interval (CI): 29, 52). For key secondary endpoints, median progression-free survival (mPFS) was 4.9 months (95% CI: 2.9, 6.7) and median overall survival (mOS) was 14.3 months (95% CI: 10.8, NE). Median response duration was not reached. Of the patients who responded to treatment with tarlatamab at 10 mg dose, 58% experienced at least six months of response and 55% of responses were ongoing at data cutoff.

"Small cell lung cancer has represented one of the greatest challenges in cancer treatment, where there has been little progress against this deadly tumor type in decades," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "The tarlatamab results show the potential for this BiTE® molecule in a common solid tumor. We look forward to discussing these potentially registrational data with regulatory authorities."

There were no new safety signals observed compared to Phase 1 study. Discontinuations due to treatment-related adverse events (TRAEs) were infrequent (4%). The most common treatment-emergent adverse events (TEAEs) reported among patients in the tarlatamab 10 mg group, were cytokine release syndrome (CRS; 49%), pyrexia (38%), decreased appetite (25%) and dysgeusia (24%). CRS was largely confined to the first and second dose, predominantly grade 1 or 2 and were generally managed with supportive care. At the tarlatamab 10 mg dose, grade 3 CRS was low (0%) and grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) and associated neurologic events were not observed (0%). There were no reported grade 4 or 5 cases for either of these two adverse events.

"In the current third-line treatment of SCLC, patients face a dire prognosis, with response rates ranging between 14 and 21 percent and median overall survival less than six months," said Luis Paz-Ares, M.D., Ph.D., chairman, Medical Oncology Department, Hospital Doce de Octubre; Head, Lung Cancer Unit, National Oncology Research Center (CNIO); associate professor, Universidad Complutense.

About Tarlatamab
Tarlatamab is an investigational, targeted immunotherapy engineered by Amgen researchers that brings a patient's own T cells in close proximity to SCLC cells by binding both CD3 on T cells and DLL3 on SCLC cells. This results in the formation of an immunological synapse with lysis of the cancer cell.[1,2] DLL3 represents an exciting therapeutic target for patients with SCLC, as approximately 85% to 94% of patients have expression of DLL3 on the cell surface of SCLC cells, with minimal expression in normal cells.[3,4,5]

In a Phase 1 study, tarlatamab showed responses in 23.0% of patients with encouraging durability in heavily pre-treated patients with SCLC.

Amgen is currently investigating tarlatamab in multiple trials, including DeLLphi-304, a Phase 3 study comparing tarlatamab versus standard of care chemotherapy in second-line treatment of SCLC that is enrolling patients. Amgen has plans to initiate two additional Phase 3 studies of tarlatamab in earlier settings of SCLC.

About Small Cell Lung Cancer (SCLC)
SCLC is one of the most aggressive and devastating solid tumors with a median survival of approximately 12 months following initial therapy and a 7% five-year relative survival rate across all stages [6,7,8] Of the 2.2M+ patients diagnosed with lung cancer worldwide each year, SCLC comprises 15% of cases.[9,10]

Despite initial high response rates to platinum-based first-line chemotherapy, patients quickly develop resistance to second-line and subsequent therapies and face a median time of survival of 10 to 12 months after diagnosis.[11] Furthermore, there are currently no approved therapeutic options in the third-line treatment of SCLC.

About Tarlatamab Clinical Trials
Amgen's robust tarlatamab development program includes the DeLLphi clinical trials, which evaluate tarlatamab as a monotherapy and as part of combination regimens in earlier stages of SCLC.

Tarlatamab is being investigated in multiple studies, including DeLLphi-301, a potentially registrational Phase 2 study to evaluate the efficacy, safety, tolerability, and pharmacokinetics of tarlatamab in third-line or later relapsed/refractory SCLC.

Additional clinical studies underway include DeLLphi-302, a Phase 1b combination study evaluating tarlatamab in combination with an anti-PD-1 therapy in second-line or later SCLC; DeLLphi-303, a Phase 1b study investigating tarlatamab in combination with standard of care therapies in first-line SCLC; and DeLLphi-304, a randomized Phase 3 trial comparing tarlatamab monotherapy with standard of care therapy in patients with SCLC

who have relapsed following first-line platinum-based chemotherapy.[12] Amgen also plans to initiate two additional Phase 3 studies of tarlatamab in earlier settings of SCLC.

For more information, please visit www.tarlatamabclinicaltrials.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 https://www.amgenoncology.com/bite-platform.html.

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 2023, Amgen was named one of "America's Greatest Workplaces" by Newsweek, one of "America's Climate Leaders" by USA Today and one of the "World's Best Companies" by TIME.

For more information, visit Amgen.com and follow us on X (formerly known as Twitter), LinkedIn, Instagram, TikTok, YouTube and Threads.

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 Kyowa-Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Teneobio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the Horizon Therapeutics plc acquisition (including the prospective performance and outlook of Horizon's business, performance and opportunities and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), 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 on our business, outcomes, progress, 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. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate Horizon, and such acquisition or integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of our information technology systems 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.

CONTACT: Amgen, Thousand Oaks
Elissa Snook, 609-251-1407 (media)
Jessica Akopyan, 805-440-5721 (media)
Justin Claeys, 805-313-9775 (investors)

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