AMGEN ANNOUNCES POSITIVE TOPLINE PHASE 3 RESULTS FOR BEMARITUZUMAB IN FIBROBLAST GROWTH FACTOR RECEPTOR 2b (FGFR2b) POSITIVE FIRST-LINE GASTRIC CANCER

June 30, 2025

At an Interim Analysis, Bemarituzumab Plus Chemotherapy Significantly Improved Overall Survival in People With FGFR2b Overexpression Compared to Chemotherapy Alone

THOUSAND OAKS, Calif., June 30, 2025 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the Phase 3 FORTITUDE-101 clinical trial evaluating first-line bemarituzumab plus chemotherapy (mFOLFOX6) met its primary endpoint of overall survival (OS) at a pre-specified interim analysis.

Bemarituzumab plus chemotherapy demonstrated a statistically significant and clinically meaningful improvement in OS as compared to placebo plus chemotherapy in people living with unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) cancer with FGFR2b overexpression and who are non-HER2 positive. FGFR2b overexpression was defined as 2+/3+ staining in ≥10% of tumor cells by centrally performed immunohistochemistry (IHC) testing.

Gastric cancer is the fifth leading cause of cancer-related death worldwide, with nearly one million new cases and over 650,000 deaths globally each year [1], highlighting a critical unmet medical need.

"Most patients with gastric cancer are diagnosed at an advanced stage, with poor prognosis, low survival rates and limited therapeutic options," said Jay Bradner, M.D., executive vice president of Research and Development at Amgen. "These first positive top-line results of an FGFR2b targeted monoclonal antibody from our Phase 3 FORTITUDE-101 study mark a meaningful advance in the development of effective targeted therapy for gastric cancer."

The most common treatment-emergent adverse events (>25%) in patients treated with bemarituzumab plus chemotherapy were reduced visual acuity, punctate keratitis, anaemia, neutropenia, nausea, corneal epithelium defect and dry eye. While ocular events were consistent with the Phase 2 experience and observed in both arms, they occurred with greater frequency and severity in the Phase 3 bemarituzumab arm.

Detailed results from the trial will be shared at a future medical meeting.

FORTITUDE-101 was conducted with the support of Zai Lab. Zai Lab holds co-development and commercialization rights for bemarituzumab for mainland China, Hong Kong, Macau, and Taiwan.

A Phase 3 study of bemarituzumab plus chemotherapy and nivolumab is also ongoing in patients with first-line gastric cancer, with a data readout anticipated in H2 2025.

About FGFR2b
The FGFR2b protein (also known as fibroblast growth factor receptor 2b) is an emerging biomarker which, when overexpressed, promotes aberrant signaling leading to tumor cell proliferation.[2]

The FGFR2b protein is overexpressed by G/GEJ tumor cells in approximately 38% of patients with advanced G/GEJ cancer. FGFR2b protein overexpression is defined as 2+/3+ staining intensity on tumor cell membrane, as detected by immunohistochemistry (IHC) testing. In approximately 16% of patients with advanced G/GEJ cancer, FGFR2b protein overexpression is observed on ≥10% of tumor cells by IHC.[3]

About FORTITUDE-101
FORTITUDE-101 is a randomized, multi-center, double-blind, placebo-controlled Phase 3 study of bemarituzumab plus mFOLFOX6 versus placebo plus mFOLFOX6 as first-line therapy in advanced G/GEJ cancer with FGFR2b overexpression. The FORTITUDE-101 trial spanned 300 sites across 37 countries, with 547 patients enrolled.

The primary outcome measure of the trial is overall survival in patients with FGFR2b ≥10% 2+/3+ tumor cell staining. Key secondary outcome measures include progression-free survival and overall response rate. Candidates were excluded from the trial if they were known to be human epidermal growth factor receptor 2 (HER2) positive. FORTITUDE-101 included more comprehensive ocular-related monitoring than previous studies of bemarituzumab.

About Amgen
Amgen discovers, develops, manufactures and delivers innovative medicines to help millions of patients in their fight against some of the world's toughest diseases. More than 40 years ago, Amgen helped to establish the biotechnology industry and remains on the cutting-edge of innovation, using technology and human genetic data to push beyond what's known today. Amgen is advancing a broad and deep pipeline that builds on its existing portfolio of medicines to treat cancer, heart disease, osteoporosis, inflammatory diseases and rare diseases.

In 2024, Amgen was named one of the "World's Most Innovative Companies" by Fast Company and one of "America's Best Large Employers" by Forbes, among other external recognitions. Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average®, and it is also part of the Nasdaq-100 Index®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

For more information, visit Amgen.com and follow Amgen on X, LinkedIn, Instagram, 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 BeOne Medicines Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast), our acquisitions of ChemoCentryx, Inc. or Horizon Therapeutics plc (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, including those resulting from geopolitical relations and government actions. 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. 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, 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 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 sustainability 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.

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