Phase 2 Fight Trial Continues To Show Improved Overall Survival With Bemarituzumab Plus Chemotherapy In Patients With FGFR2b+ Gastric And Gastroesophageal Cancers

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Median Overall Survival was 5.7 Months Longer in Patients Treated with Bemarituzumab Compared to Chemotherapy Alone

Full Results Presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting

THOUSAND OAKS, Calif., June 4, 2021 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced updated results for investigational bemarituzumab in combination with chemotherapy from the Phase 2 FIGHT trial. The trial evaluated bemarituzumab plus chemotherapy (mFOLFOX6) versus chemotherapy alone in patients with FGFR2b-positive, HER2-negative frontline advanced gastric or gastroesophageal junction cancers (GEJ). New data includes median overall survival (OS), a secondary endpoint that was reached with longer follow-up, as well as additional analyses of patient subgroups.

With a median follow-up of 12.5 months, the addition of bemarituzumab to chemotherapy resulted in a median OS of 19.2 months versus 13.5 months for chemotherapy alone in all randomized patients (n=155, HR: 0.6; 95% CI: 0.38, 0.94). In an exploratory pre-specified subgroup analysis, in patients with ≥10% of tumor cells overexpressing FGFR2b by immunohistochemistry (IHC), the median OS for bemarituzumab was 25.4 months versus 11.1 months (n=96, HR: 0.41; 95% CI: 0.23, 0.74).

The incidence of all grade adverse events was similar in the bemarituzumab plus chemotherapy and chemotherapy only arm of the study (100% versus 98.7%, respectively). The incidence of corneal adverse events was higher in the bemarituzumab plus chemotherapy arm versus the chemotherapy arm (all grade AEs 67.1% versus 10.4%), with dry eye reported as the most common corneal event (26.3%). The majority of the corneal adverse events were reversible.

The results were presented today in an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting taking place virtually from June 4-8, 2021.

"Gastric cancer is the fourth leading cause of cancer death globally and 30% of frontline HER2-negative gastric cancer patients have tumors that overexpress FGFR2b," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "These updated results underscore the benefits that bemarituzumab plus chemotherapy may bring to patients who have been fighting this aggressive disease with chemotherapy alone. We now look forward to advancing bemarituzumab into Phase 3 development."

More than one million new gastric cancer cases are diagnosed annually, and gastric cancer is particularly prevalent in Asia.[1,2] Approximately 80 to 85% of advanced gastric and GEJ cancers are HER2-negative, and approximately 30% of these tumors overexpress FGFR2b.[3,4]

"These updated results further validate our work on the role of FGFR2b overexpression in gastroesophageal cancer and demonstrate that treatment with bemarituzumab in combination with chemotherapy can deliver a clinically significant reduction in the risk of disease progression for patients whose tumors overexpress FGFR2b," said Daniel V.T. Catenacci, MD, PhD, medical oncologist and principal investigator at the University of Chicago.

In April 2021, bemarituzumab was granted Breakthrough Therapy Designation by the U.S. FDA based upon a subset of patients from the FIGHT trial who showed at least 10% of tumor cells overexpressing FGFR2b. Amgen continues to investigate the role of FGFR2b and will continue to work with regulatory agencies on next steps, including Phase 3 development, to bring this potential first-in-class therapy to patients.

About Bemarituzumab

Bemarituzumab (anti-FGFR2b) is a Phase 3 ready, potential first-in-class, investigational targeted antibody that is designed to block specific fibroblast growth factors (FGFs) from binding and activating FGFR2b, inhibiting several downstream pro-tumor signaling pathways and potentially slowing cancer progression. Bemarituzumab is being developed in gastric and GEJ cancer as a targeted therapy for tumors that overexpress FGFR2b. The company is also evaluating the potential for bemarituzumab in other cancers that overexpress FGFR2b.

Zai Lab (Shanghai) Co. Ltd. was granted an exclusive license to develop and commercialize bemarituzumab in Greater China, and Zai Lab collaborated with Five Prime on the Phase 2 FIGHT trial in Greater China.

About FIGHT

The FIGHT trial evaluated bemarituzumab plus chemotherapy (mFOLFOX6) versus chemotherapy alone in patients with FGFR2b-positive, HER2-negative frontline advanced gastric or GEJ cancer. In the study, treatment with bemarituzumab plus chemotherapy demonstrated clinically significant and substantial improvements in the primary endpoint of progression-free survival (PFS) and secondary endpoint of overall survival (OS) in the patient population in which at least 10% of tumor cells overexpressed FGFR2b. Additional analysis showed a positive correlation between benefit and the prevalence of FGFR2b+ tumor cells, affirming both the importance of the FGFR2b target and the activity of bemarituzumab against this target. The Breakthrough Therapy Designation was granted based upon this subset of patients who showed at least 10% of tumor cells overexpressing FGFR2b.

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.

At Amgen, we're advancing oncology at the speed of life™.

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 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), or the Five Prime Therapeutics, Inc. 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 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. 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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