Amgen's Investigational Targeted Treatment Bemarituzumab Granted Breakthrough Therapy Designation

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Potential First-in-Class Therapy for a Subset of Gastric and Gastroesophageal Cancers That Overexpress Fibroblast Growth Factor Receptor 2 (FGFR2b)

Designation is Supported by Results From the Phase 2 FIGHT Trial

THOUSAND OAKS, Calif., April 19, 2021 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for investigational bemarituzumab as first-line treatment for patients with fibroblast growth factor receptor 2b (FGFR2b) overexpressing and human epidermal growth factor receptor 2 (HER2)-negative metastatic and locally advanced gastric and gastroesophageal (GEJ) adenocarcinoma in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin), based on an FDA-approved companion diagnostic assay showing at least 10% of tumor cells overexpressing FGFR2b.

"The FIGHT trial is the first study to evaluate targeting the overexpression of FGFR2b in cancer. Bemarituzumab demonstrated clinically meaningful outcomes in key endpoints for patients with advanced gastric or gastroesophageal cancer as a frontline therapy," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Amgen looks forward to further investigating the role of FGFR2b and will continue to work with regulatory agencies on next steps to bring this potential first-in-class, frontline therapy to patients."

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 patients with advanced gastric and GEJ cancers are HER2-negative, and approximately 30% of these patients present with FGFR2b overexpression.[3,4]

Following sotorasib, bemarituzumab is the second asset in Amgen's oncology portfolio to receive Breakthrough Therapy Designation in the past six months. A Breakthrough Therapy Designation is designed to expedite the development and regulatory review of medicines that may demonstrate substantial improvement on a clinically significant endpoint over available medicines.[5]

The FIGHT trial evaluated bemarituzumab plus chemotherapy (mFOLFOX6) versus chemotherapy alone in patients with FGFR2b+, non-HER2 positive 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.

Amgen acquired Five Prime Therapeutics on April 16, 2021. In addition to bemarituzumab, Five Prime's pipeline complements Amgen's efforts to bring innovative therapies to oncology patients.

About Bemarituzumab
Bemarituzumab (anti-FGFR2b) is a potential first-in-class investigational targeted antibody that is designed to block 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 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.

To learn more about Amgen's innovative pipeline with diverse modalities and genetically validated targets, please visit AmgenOncology.com. 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 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. 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. There can be no guarantee that we will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the Five Prime acquisition. Nor can there be any guarantee that bemarituzumab will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that such product will be successfully commercialized even if regulatory approvals are obtained. In particular, our expectations could be affected by, among other things: potential regulatory actions or delays with respect to the development of bemarituzumab; the potential that the strategic benefits, synergies or opportunities expected from the acquisition may not be realized or may take longer to realize than expected; and the successful integration of Five Prime into Amgen subsequent to the closing of the transaction and the timing of such integration.

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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