Analysis Of Rilotumumab (AMG 102) Data Identifies A Potential Predictive Biomarker For Patients With Gastric Or Gastroesophageal Cancer

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Data Links MET Protein Expression to Rilotumumab Clinical Response
Rilotumumab Moving into Phase 3 Study in Advanced Gastric Cancer

THOUSAND OAKS, Calif., May 16, 2012 /PRNewswire/ -- Amgen (NASDAQ: AMGN) announced today results from an exploratory biomarker analysis evaluating MET expression as a predictor of clinical response to rilotumumab (AMG 102). This analysis, conducted on a previously reported Phase 2 study of rilotumumab in patients with locally advanced or metastatic gastric or gastroesophageal cancer, showed that treatment with rilotumumab in combination with chemotherapy improved median overall survival (OS) in patients whose tumors exhibited high MET protein expression. Full results of the study will be presented in an oral presentation at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) on June 2 (Abstract 4005, 4:45 p.m. - 5:00 p.m. CDT, E Hall D1).

Rilotumumab is an investigational fully human monoclonal antibody designed to inhibit the hepatocyte growth factor/scatter factor (HGF/SF): MET pathway. In this exploratory analysis, the addition of rilotumumab to chemotherapy in patients with gastric tumors with high MET expression improved median OS from 5.7 months to 11.1 months (HR = 0.29, 95 percent CI, 0.11 - 0.76). Conversely, in patients with gastric tumors with low MET expression, the addition of rilotumumab to chemotherapy was associated with a trend towards unfavorable OS (HR = 1.84, 95 percent CI, 0.78 - 4.34). These results have led Amgen to plan a Phase 3 study to confirm the efficacy of rilotumumab in advanced gastric and gastroesophageal cancer with high MET expression.

"These data are the first to demonstrate a potential biomarker for treatment with rilotumumab in gastric cancer, the second leading cause of cancer deaths worldwide," said Michael Severino, M.D., senior vice president, global development and corporate chief medical officer at Amgen. "Personalized medicine has the potential to transform cancer care, and by leveraging our understanding of biology and the mechanism of disease, we hope to identify safe and effective new treatments for patients who aren't well-served by current therapies."

Primary results of the study were presented at the 2011 European Multidisciplinary Cancer Congress and showed that the primary endpoint of progression-free survival (PFS) had a trend towards a better outcome with rilotumumab plus chemotherapy. The addition of rilotumumab to chemotherapy improved median PFS from 4.2 months to 5.6 months (HR = 0.64, 80 percent CI, 0.48 – 0.85). The secondary endpoint of OS also trended in favor of rilotumumab, with improved median OS from 8.9 months to 11.1 months (HR = 0.73, 80 percent CI, 0.53 – 1.01).

The most common adverse events seen in the rilotumumab plus chemotherapy arms included peripheral edema, neutropenia, anemia, thrombocytopenia and deep vein thrombosis. There were no major differences in adverse events between the two rilotumumab arms.

Amgen and Dako have entered into a collaboration to develop and evaluate the use of a companion diagnostic test in the development of rilotumumab.

In addition to the results from this study, data from studies of 12 Amgen investigational molecules and marketed products will be presented at the ASCO Annual Meeting. These include results from studies of the immunotherapy talimogene laherparepvec, pipeline molecules such as blinatumomab (AMG 103) and AMG 386, and marketed products. A complete listing of Amgen abstracts of interest can be found at www.amgen.com/media/amgen_asco_2012.html. Abstracts are available online at www.asco.org.

Phase 2 Study Design
In this Phase 2, three-arm trial, 121 patients were randomized 1:1:1 to receive epirubicin, cisplatin and capecitabine (50mg/m(2) IV day 1, 60mg/m(2) IV day 1, 625mg/m(2) BID orally days 1-21, respectively) in combination with two different dose levels of rilotumumab (Arm A 15 mg/kg Q3W, n=40; Arm B 7.5 mg/kg Q3W, n=42) or placebo (Arm C, n=39). The primary endpoint of the study was PFS. Secondary endpoints included OS, objective response rate (ORR) and safety. In the biomarker analysis, 90 patients were evaluated for MET protein levels using an immunohistochemistry test. Twenty-seven patients from the rilotumumab treatment arms and 11 patients who received placebo were found to have tumors with high MET expression, defined as greater than 50 percent of tumor cells testing positive for the MET protein.

About Gastric Cancer
Gastric, or stomach, cancer is the second most common cause of cancer-related death in the world, accounting for 736,000 deaths worldwide in 2008. The highest mortality rates are in Eastern Asia.[1] An estimated 21,320 new cases of gastric cancer will be diagnosed in the United States in 2012, and about 10,540 Americans will die from this type of cancer.[2] Gastric cancer is a disease that mostly affects older people with nearly two-thirds of patients age 65 and older.[3]

About Amgen
Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and vital medicines, visit www.amgen.com. Follow us on www.twitter.com/amgen.

Forward-Looking Statements
This news release contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including 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 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 (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of May 16, 2012 and expressly disclaims any duty to update information contained in this news release.

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. 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 after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products are affected by the reimbursement policies imposed by third-party payors, 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 as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, 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 and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, 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.

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 (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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[1] Cancer. World Health Organization website. http://www.who.int/mediacentre/factsheets/fs297/en/. Accessed April 26, 2012.
[2] Stomach Cancer. American Cancer Society website. http://www.cancer.org/Cancer/StomachCancer/DetailedGuide/stomach-cancer-key-statistics. Accessed April 26, 2012.
[3] Stomach Cancer. American Cancer Society website. http://www.cancer.org/Cancer/StomachCancer/DetailedGuide/stomach-cancer-key-statistics. Accessed April 26, 2012.

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