New AMG 386 Data Demonstrate Promising Antitumor Activity in Patients With Recurrent Ovarian Cancer

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AMG 386 Treatment Response Increased With Dose And Exposure
AMG 386 Moving Into Phase 3 For Recurrent Ovarian Cancer
Separately, Two Analyses Provide Evidence Of Biomarker As Predictor Of Tumor Response To Motesanib

THOUSAND OAKS, Calif., June 6, 2010 /PRNewswire via COMTEX/ --Amgen (Nasdaq: AMGN) today announced that AMG 386, combined with paclitaxel, demonstrated antitumor activity in a randomized Phase 2 trial involving 161 patients with recurrent ovarian cancer. The results are being presented for the first time in an oral presentation at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting. (Abstract Number: 5000)

AMG 386 is a first-in-class investigational peptibody that is designed to block angiogenesis by inhibiting angiopoietin-1 and -2 (Ang1 and Ang2). Angiopoietins interact with the Tie2 receptor, which mediates vascular remodeling. Ang1 and Ang2 are thought to play opposing roles, and the maturation of blood vessels appears to be controlled by their precise balance.

"The reality of ovarian cancer is that 80 percent of women diagnosed in later stages will experience recurrence, often multiple times, and eventually die from the disease," said Beth Karlan, M.D., director of the Women's Cancer Research Institute at Cedars-Sinai's Samuel Oschin Comprehensive Cancer Institute and director of Cedars-Sinai Medical Center's Division of Gynecologic Oncology. "In this study, AMG 386 showed promising antitumor activity and extended progression-free survival."

Patients were randomized to receive paclitaxel via IV weekly, three weeks on and one week off, plus AMG 386 at 10 mg/kg (Arm A, n=53), AMG 386 at 3 mg/kg (Arm B, n=53), or placebo (Arm C, n=55).

Median progression-free survival (PFS), the study's primary endpoint, in the 10 mg/kg arm was 7.2 months versus 5.7 months in the 3 mg/kg arm and 4.6 months in the placebo group (80 percent CI, 0.59 - 0.98; p=0.17). The objective response rate, per RECIST, was 37 percent in the 10 mg/kg arm versus 19 percent in the 3 mg/kg arm and 27 percent in the placebo group. Response rate measured by serum CA-125 levels, per the guidance from the Gynecologic Cancer Intergroup (GCIG), was 71 percent in the 10 mg/kg arm versus 58 percent in the 3 mg/kg arm and 28 percent in the placebo group.

Grade 3 or higher adverse events (AEs), where the difference in incidence was more than five percent in the AMG 386 arm than the placebo arm, included: hypokalemia (Arm A/B/C percentages 12/11/4), peripheral neuropathy (10/2/4), anorexia (2/6/0), neutropenia (8/9/4), and dyspnea (2/9/4).

Other grade 3 or higher AEs of interest included thromboembolic events (arterial 2/2/0; venous 6/6/9). No grade 3 or higher hypertension was observed and there were no bowel perforations in patients treated with AMG 386. No treatment-related deaths occurred in the study.

The results of a population pharmacokinetic/pharmacodynamic analysis were presented separately in a poster at the Annual Meeting. This analysis suggests that investigation using higher doses of AMG 386 for patients with ovarian cancer is warranted. (Abstract Number: 5042)

Two Analyses Suggest Placental Growth Factor May be a Biomarker of Therapeutic Response to Motesanib

Results of two analyses evaluating biomarkers as predictors of response to treatment with motesanib were also presented at the meeting. Motesanib is an investigational, orally-administered, small molecule antagonist of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3, platelet-derived growth factor receptor, and stem cell factor receptor. It is being investigated for its potential to inhibit the activity of all three VEGF receptors, which are key drivers of angiogenesis and lymphangiogenesis.

In the first study, a panel of five biomarkers was evaluated in patients with locally recurrent or advanced HER2-negative metastatic breast cancer who were treated with motesanib, bevacizumab, or placebo in combination with paclitaxel. Results showed that increases in circulating placental growth factor (PlGF) were associated with subsequent tumor response to treatment with motesanib plus paclitaxel. (Abstract Number: 1048)

In a separate study, a variety of biomarkers were evaluated in patients with progressive, advanced thyroid cancer, advanced non-squamous, non-small cell lung cancer, and locally recurrent or advanced metastatic breast cancer. Data from this analysis also suggested that PlGF elevation predicts clinical outcome across tumor types in patients treated with motesanib. (Abstract Number: 3037)

Motesanib is being developed in collaboration with Takeda and Millenium, the Takeda Oncology Company.

Webcast Information

Amgen will hold an analyst/investor event at a local venue in Chicago on Monday, June 7 at 7:30 p.m. Central Time to discuss data presented at ASCO. A webcast of the event can be found on Amgen's website at http://www.amgen.com/, under Investors. The audio webcast will be archived and available for replay for at least 72 hours.

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 and 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, 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 our vital medicines, visit http://www.amgen.com/.

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 June 6, 2010 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. Further, the 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 (FDA) 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. Only the FDA can determine whether the products are safe and effective for these uses. 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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