Amgen Announces Top-Line Results Of Phase 3 Trebananib (AMG 386) TRINOVA-1 Trial In Recurrent Ovarian Cancer

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Study Meets Primary Endpoint of Progression-Free Survival

THOUSAND OAKS, Calif., June 12, 2013 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that the Phase 3 TRINOVA-1 trial evaluating trebananib plus paclitaxel versus placebo plus paclitaxel in recurrent ovarian cancer met its primary endpoint of progression-free survival (PFS). A statistically significant difference was observed in PFS with a 34 percent reduction in the risk of disease progression or death (HR = 0.66, 95 percent CI, 0.57, 0.77, p<0.001). The median PFS was 7.2 months in the trebananib arm versus 5.4 months in the control arm.

The primary analysis of overall survival (OS), a key secondary endpoint, is expected to mature in 2014 in line with previous guidance. Although an early imbalance of deaths favoring the control arm was observed, there was an overall favorable OS trend for trebananib in a pre-planned interim analysis.

"The TRINOVA-1 study is the first of three Phase 3 trials designed to evaluate the safety and efficacy of trebananib in patients with ovarian cancer," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Angiopoietin inhibition has been a focus of research at Amgen and these results suggest that the novel biology of trebananib may offer a promising approach for patients with ovarian cancer."

In the trebananib arm, the most frequently reported adverse events were localized edema, nausea and alopecia. The rate of discontinuation of investigational product due to adverse events was 20 percent in the trebananib arm versus seven percent in the control arm.

Approximately 22,240 new cases of ovarian cancer will be diagnosed in the United States in 2013.[1] More than 70 percent of women with ovarian cancer will present with advanced disease at diagnosis and up to 80 percent of them will experience disease recurrence and eventually die from their disease.[2,3]

TRINOVA-1 Trial Design (NCT01204749)
TRINOVA-1 is a Phase 3 global, multicenter, randomized, double-blind, placebo-controlled study evaluating trebananib in over 900 women with recurrent partially platinum-sensitive or -resistant (platinum-free interval of 12 months or less) epithelial ovarian, primary peritoneal or fallopian tube cancer. Patients were randomized 1:1 to receive either 15 mg/kg of intravenous trebananib weekly plus 80 mg/m^2 of intravenous paclitaxel weekly (three weeks on, one week off) or weekly intravenous placebo plus 80 mg/m^2 of intravenous paclitaxel weekly (three weeks on, one week off).

Other ongoing Phase 3 studies of trebananib include TRINOVA-2 and TRINOVA-3. TRINOVA-2 is evaluating whether trebananib plus pegylated liposomal doxorubicin (PLD) is superior to placebo plus PLD as measured by PFS in recurrent epithelial ovarian, primary peritoneal or fallopian tube cancer. TRINOVA-3 is evaluating trebananib or placebo in combination with paclitaxel and carboplatin in the first-line treatment of epithelial ovarian, primary peritoneal or fallopian tube cancer.

About Trebananib
Trebananib is an investigational peptibody designed to inhibit the angiopoietin axis. The angiopoietin axis is involved in angiogenesis, a process used by the body to grow new blood vessels, which is also involved in the pathogenesis of several diseases. Trebananib is designed to bind to both angiopoietin-1 and -2 (Ang1 and Ang2), and inhibit their interaction with the Tie2 receptor.[4,5,6] Ang1 and Ang2 each mediate separate actions upon binding with Tie2.[7,8] Ang1 impacts vessel quality while Ang2 influences vessel quantity. The angiopoietins are also involved in lymphangiogenesis, the formation of new lymphatic vessels, which plays a key role in tumor metastasis.[9]

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 people around the world in the fight against serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. 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 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 any subsequent 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 12, 2013, 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 product liability claims. 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. 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 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 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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