Amgen Announces Top-Line Secondary Endpoint Results Of Phase 3 Trebananib TRINOVA-1 Trial In Patients With Recurrent Ovarian Cancer

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Study Failed to Meet Secondary Endpoint of Overall Survival

THOUSAND OAKS, Calif., Nov. 4, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the top-line secondary endpoint results of overall survival from the Phase 3 TRINOVA-1 trial in women with recurrent platinum-resistant ovarian cancer. The study, which evaluated trebananib plus paclitaxel versus placebo plus paclitaxel, did not demonstrate a statistically significant improvement in overall survival. Median overall survival was 19.3 months in the trebananib arm versus 18.3 months in the control arm. The data will be submitted to a future medical conference and for publication.

In the previously reported primary endpoint analysis, the data demonstrated a statistically significant difference in progression-free survival for trebananib. In that analysis, patients treated with trebananib showed 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 progression-free survival was 7.2 months in the trebananib arm versus 5.4 months in the control arm.

"While the overall survival results of the TRINOVA-1 study are disappointing, this 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. "We continue to explore the potential of trebananib's novel anti-tumor mechanism of action in other cancer settings."

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. No new safety signals were detected.

Data from another trial in the recurrent platinum-resistant population (TRINOVA-2) is expected in Q4 2014. Data from a trial evaluating trebananib in combination with first-line chemotherapy treatment for patients with ovarian cancer (TRINOVA-3) is expected in 2015.

TRINOVA-1 Trial Design (NCT01204749)

TRINOVA-1 (A Study of AMG 386 or Placebo, in Combination With Weekly Paclitaxel Chemotherapy, as Treatment for Ovarian Cancer, Primary Peritoneal Cancer and Fallopian Tube Cancer) 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/m2 of intravenous paclitaxel weekly (three weeks on, one week off) or weekly intravenous placebo plus 80 mg/m2 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 progression-free survival 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.[1,2,3] Ang1 and Ang2 each mediate separate actions upon binding with Tie2.[4,5] 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.[6]

About Ovarian Cancer

About 21,980 women will be diagnosed with ovarian cancer in the U.S. in 2014 and about 14,270 women will die from ovarian cancer.[7] 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.[8,9]

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 biologics manufacturing 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 the world's largest independent biotechnology company, 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 Inc. and its subsidiaries (Amgen or us) 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 Inc., including Amgen Inc.'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 Inc.'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 Nov. 4, 2014, 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 and our partners 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 (including products of our wholly-owned subsidiaries) 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 Amgen and its partners routinely obtain patents for their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' 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. Our efforts to integrate the operations of companies we have acquired may not be successful. Cost saving initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plans. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our common stock.

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.

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