Amgen And Allergan Announce Top-Line Results From Phase 3 Study Evaluating ABP 980 Compared With Trastuzumab In Patients With Human Epidermal Growth Factor Receptor 2-Positive Early Breast Cancer

THOUSAND OAKS, Calif. and DUBLIN, July 21, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Allergan plc (NYSE:AGN) today announced results from a Phase 3 study evaluating efficacy and safety of ABP 980 compared with trastuzumab in patients with human epidermal growth factor receptor 2-positive (HER2-positive) early breast cancer. The results ruled out inferiority compared to trastuzumab but could not rule out superiority based on its primary efficacy endpoint of the difference of the percentage of patients with a pathologic complete response (pCR). The primary endpoint had a prespecified equivalence margin of +/- 13 percent and the observed upper end of the confidence interval was 13.4 percent.

Overall, adverse events were comparable between ABP 980 and trastuzumab. In the neoadjuvant phase of the study, which included chemotherapy, there were more serious adverse events reported in the ABP 980 group, the majority of which were reported by the investigators as unlikely related to investigational product. In the adjuvant phase of the study, which did not include chemotherapy, serious adverse events were comparable between treatment groups. The overall results also showed comparable immunogenicity.

"We believe this study confirms no clinically meaningful differences between ABP 980 and trastuzumab, and we look forward to continued discussions with regulatory authorities," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Biosimilars are approved based on the analytical, nonclinical and clinical data, and we believe that the totality of the evidence we've generated supports ABP 980 as highly similar to the reference product."

"These results provide significant clinical evidence that ABP 980 could be an important biosimilar treatment option for patients with HER2-positive early breast cancer," said David Nicholson, chief research and development officer, Allergan. "Allergan is committed to the continued development of ABP 980 and other biosimilars that provide safe, high-quality and effective therapies in key disease areas."

ABP 980 is being developed as a biosimilar to trastuzumab, a recombinant DNA-derived humanized monoclonal immunoglobulin G1 kappa antibody which targets HER2. Trastuzumab is approved in many regions for the treatment of HER2-positive early breast cancer, metastatic breast cancer and metastatic gastric cancer.

Amgen and Allergan are collaborating on the development and commercialization of four oncology biosimilars. Amgen has a total of nine biosimilars in development. Allergan is also independently developing biosimilars.

Study Design

This above referenced Phase 3 study was a randomized, multicenter, double-blinded, active-controlled study (study number 20120283) that evaluated safety and efficacy of ABP 980 compared to trastuzumab in adult female patients with HER2-positive early breast cancer. There were 725 patients randomized, with 364 patients in the ABP 980 group and 361 patients in the trastuzumab group.

In the neoadjuvant phase, enrolled patients received run-in chemotherapy consisting of epirubicin and cyclophosphamide (EC) every three weeks (Q3W) for four cycles. Once run-in chemotherapy was completed, patients with adequate cardiac function were randomized 1:1 to receive investigational product (ABP 980 or trastuzumab), plus paclitaxel, Q3W for four cycles. Surgery (breast and sentinel node or axillary lymph node resection) was complete three to seven weeks after the last dose of investigational product in the neoadjuvant phase, and pCR was analyzed.

In the adjuvant phase, following surgery, patients received investigational product (ABP 980 or trastuzumab) Q3W for up to one year from the first day of investigational product administered in the neoadjuvant phase. Patients who received ABP 980 during the neoadjuvant phase continued to receive ABP 980 Q3W for the adjuvant phase. Patients who received trastuzumab during the neoadjuvant phase received either ABP 980 or trastuzumab Q3W for the adjuvant phase. The allocation to a treatment group during the neoadjuvant or adjuvant phase occurred at randomization.

The primary analysis was conducted when the last patient completed the surgery following the neoadjuvant therapy. Clinical equivalence was assessed by comparing the confidence interval of the risk difference and risk ratio of the pCR in breast tissue and axillary lymph nodes with the prespecified equivalence margins. The final analysis of safety will be conducted when the last patient has completed their last study assessment in the adjuvant phase.

About HER2-Positive Early Breast Cancer

HER2-positive early breast cancer is a breast cancer that tests positive for a protein called human epidermal growth factor receptor 2 (HER2), which promotes the growth of cancer cells.[1] Approximately 20 percent of all breast cancers are HER2-positive.[2] Breast cancer is the second leading cause of cancer death among women and each year it is estimated that over 230,000 women in the United States will be diagnosed.[3] HER2-positive breast cancers tend to grow and spread more aggressively than HER2-negative breast cancers.[1]

About ABP 980

ABP 980 is being developed as a biosimilar to trastuzumab, a recombinant DNA-derived humanized monoclonal immunoglobulin G1 kappa antibody approved in many regions for the treatment of HER2-overexpressing early breast cancer, metastatic breast cancer and metastatic gastric cancer. The active ingredient of ABP 980 is a humanized monoclonal antibody which has the same amino acid sequence as trastuzumab. ABP 980 has the same pharmaceutical dosage form and strength as trastuzumab (US) and trastuzumab (EU).

About the Amgen and Allergan Collaboration

In December 2011, Amgen and Allergan plc. (then Watson Pharmaceuticals, Inc.) formed a collaboration to develop and commercialize, on a worldwide basis, four oncology antibody biosimilar medicines. This collaboration reflects the shared belief that the development and commercialization of biosimilar products will not follow a pure brand or generic model, and will require significant expertise, infrastructure, and investment to ensure safe, reliably supplied therapies for patients. Under the terms of the agreement, Amgen will assume primary responsibility for developing, manufacturing and initially commercializing the oncology antibody products.

About Amgen Biosimilars

Amgen Biosimilars is committed to building upon Amgen's experience in the development and manufacturing of innovative human therapeutics to expand Amgen's reach to patients suffering from serious illnesses. Biosimilars offer the potential to increase patient access to vital medicines, and Amgen is well positioned to leverage its more than 35 years of experience in biotechnology to create high-quality biosimilars and reliably supply them to patients worldwide.

For more information, visit www.amgenbiosimilars.com (http://www.amgenbiosimilars.com/) and follow us www.twitter.com/amgenbiosim (http://www.twitter.com/amgenbiosim).

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 (http://www.amgen.com/) and follow us on www.twitter.com/amgen (http://www.twitter.com/amgen).

About Allergan
Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a unique, global pharmaceutical company and a leader in a new industry model – Growth Pharma. Allergan is focused on developing, manufacturing and commercializing innovative branded pharmaceuticals, high-quality generic and over-the-counter medicines and biologic products for patients around the world.

Allergan markets a portfolio of best-in-class products that provide valuable treatments for the central nervous system, eye care, medical aesthetics, gastroenterology, women's health, urology, cardiovascular and anti-infective therapeutic categories, and operates the world's third-largest global generics business, providing patients around the globe with increased access to affordable, high-quality medicines. Allergan is an industry leader in research and development, with one of the broadest development pipelines in the pharmaceutical industry and a leading position in the submission of generic product applications globally.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives.

For more information, visit Allergan's website at www.allergan.com (http://www.allergan.com/) and follow us on https://twitter.com/allergan (https://twitter.com/allergan).

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 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 reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and 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 after they are on the market.

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. 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. 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 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. 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. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. 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.

Allergan plc Forward-Looking Statements

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2015 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (certain of such periodic public filings having been filed under the "Actavis plc" name). Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

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