Amgen And Allergan Present Phase 3 Data On Biosimilar Trastuzumab Candidate ABP 980 At The European Society For Medical Oncology 2017 Congress

September 9, 2017

Study Between ABP 980 and Trastuzumab in Patients With HER2-Positive Early Breast Cancer Adds to the Totality of Evidence of Biosimilarity

THOUSAND OAKS, Calif. and DUBLIN, Sept. 9, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Allergan plc. (NYSE:AGN) today announced data from a Phase 3 study evaluating the efficacy and safety of ABP 980, a Herceptin® (trastuzumab) biosimilar, compared with the originator product in patients with human epidermal growth factor receptor 2-positive (HER2-positive) early breast cancer. Results from the neoadjuvant efficacy phase of the study, including pathologic complete response assessed both by local investigators and also by independent pathology review, were presented today during a poster discussion at the European Society for Medical Oncology (ESMO) 2017 Congress. Efficacy, safety and immunogenicity data support ABP 980 as a trastuzumab biosimilar and add to the totality of evidence currently under review by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

"Biosimilars have the potential to provide more patients access to high-quality therapies with proven safety and efficacy profiles," said Serafin Morales, M.D., medical oncologist, University Hospital Arnau de Vilanova, Lleida, Spain. "The results presented today add to the data package demonstrating similarity between ABP 980 and trastuzumab."

The co-primary endpoints of the study were risk difference (RD) and risk ratio (RR) of pathologic complete response in breast tissue and axillary lymph nodes, and the prespecified equivalence margins were +/-13 percent for RD and 0.759 to 1.318 for RR. According to local review, 48 percent and 40.5 percent of patients in the ABP 980 arm and trastuzumab arm, respectively, achieved pathologic complete response. RD and RR of pathologic complete response were 7.3 percent (90 percent CI: 1.2, 13.4) and 1.19 (90 percent CI: 1.033, 1.366) respectively. Based on central independent review, which was conducted as part of a sensitivity analysis, 47.8 percent and 41.8 percent in the ABP 980 arm and trastuzumab arm, respectively, achieved pathologic complete response. RD and RR of pathologic complete response respectively were 5.8 percent (90 percent CI: -0.5, 12.0) and 1.14 (90 percent CI: 0.993, 1.312).

Frequency, type and severity of adverse events were similar between ABP 980 and trastuzumab. No new safety signals compared to the known safety profile of trastuzumab were detected.

"At the heart of Amgen's commitment to biosimilars is our mission to serve patients. We are leveraging our more than 35 years of biotechnology experience and using the same personnel, services and manufacturing expertise from the company's innovative business to produce high-quality, reliably supplied biosimilars for some of the most complex diseases," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The results presented today reinforce the potential of ABP 980 for breast cancer patients, and we look forward to continued discussions with regulatory authorities."

"Allergan is proud to be collaborating with Amgen on the development of several oncology biosimilars that require significant expertise, infrastructure and investment to ensure safe therapies for patients," said David Nicholson, Ph.D., chief research and development officer, Allergan. "We are excited about the progress of ABP 980 and are committed to its development in hopes of providing patients with an effective alternative option."

Amgen and Allergan are collaborating on the development and commercialization of four oncology biosimilars. Amgen has a total of 10 biosimilars in its portfolio, one of which has been approved by the FDA and European authorities.

ABP 980 Phase 3 Study Design

The ABP 980 Phase 3 LILAC 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 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 either ABP 980 or trastuzumab in the neoadjuvant phase, and pathologic complete response was analyzed.

In the adjuvant phase, following surgery, patients received ABP 980 or trastuzumab Q3W for up to one year from the first day either product was 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 either underwent a single switch to ABP 980 or continued on trastuzumab Q3W for the adjuvant phase. The allocation to a treatment group during the neoadjuvant or adjuvant phase occurred by randomization, as did the single switch from trastuzumab to ABP 980 after the neoadjuvant phase.

The primary analysis was conducted when the last patient completed the surgery following the neoadjuvant therapy. Statistical equivalence was assessed by comparing the confidence interval of the RD and RR of the pathologic complete response in breast tissue and axillary lymph nodes with the prespecified equivalence margins.

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 most common cancer in Europe for females, and the most common cancer overall, with more than 464,000 new cases diagnosed each year.[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, adjuvant breast cancer, metastatic breast cancer and metastatic gastric cancer. The active ingredient of ABP 980 is a humanized monoclonal antibody that has the same amino acid sequence as trastuzumab. ABP 980 has the same pharmaceutical dosage form and strength as trastuzumab. In March and July of 2017 respectively, Amgen and Allergan submitted a Marketing Authorization Application to the EMA and a Biologics License Application to the FDA for ABP 980.

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 with serious illnesses. Biosimilars will help to maintain Amgen's commitment to connect patients with 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 and follow us on www.twitter.com/amgenbiosim.

About Amgen's Commitment to Oncology
Amgen Oncology is committed to helping patients take on some of the toughest cancers, such as those that have been resistant to drugs, those that progress rapidly through the body and those where limited treatment options exist. Amgen's supportive care treatments help patients combat certain side effects of strong chemotherapy, and our targeted medicines and immunotherapies focus on more than a dozen different malignancies, ranging from blood cancers to solid tumors. With decades of experience providing therapies for cancer patients, Amgen continues to grow its portfolio of innovative and biosimilar oncology medicines.

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 and follow us on www.twitter.com/amgen.

About Allergan plc
Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical company and a leader in a new industry model – Growth Pharma. Allergan is focused on developing, manufacturing and commercializing branded pharmaceuticals, devices and biologic products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, the Company's R&D model, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. This approach has led to Allergan building one of the broadest development pipelines in the pharmaceutical industry with 70+ mid-to-late stage pipeline programs in development.

Our Company's success is powered by our more than 16,000 global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is right.

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 every day.

For more information, visit Allergan's website at www.Allergan.com.

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.

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, including our devices, 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. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. 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.

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 FDA, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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