



Amgen And Allergan Submit Biosimilar Biologics License Application For ABP 980 To US Food And Drug Administration

July 31, 2017

Filing for ABP 980, a Biosimilar Candidate to Herceptin® (trastuzumab), Supported by Phase 3 Data in Patients With HER2-Positive Early Breast Cancer

THOUSAND OAKS, Calif., July 31, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Allergan plc. (NYSE:AGN) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ABP 980, a biosimilar candidate to Herceptin® (trastuzumab). Amgen and Allergan are collaborating on four oncology biosimilar medicines, including ABP 980 which is the second to be submitted for FDA approval.

"The submission of ABP 980 for FDA review is an exciting milestone and speaks to our joint commitment with Allergan to deliver quality oncology biosimilars to patients," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Approval of ABP 980 would provide more patients access to a high-quality therapy with a proven safety and efficacy profile. We look forward to further discussions with the FDA."

"Today's submission is our second U.S. biosimilar submission in less than a year as part of our collaboration with Amgen," said David Nicholson, chief R&D officer at Allergan. "We're proud of the progress we've made so far and look forward to continuing our work to bring more biosimilars to market."

ABP 980 is a biosimilar candidate to trastuzumab, a recombinant DNA-derived humanized monoclonal immunoglobulin G1 kappa antibody that targets HER2. Trastuzumab is approved for the treatment of HER2-positive adjuvant breast cancer, metastatic breast cancer and metastatic gastric cancer in the U.S.

The BLA submission includes analytical, pharmacokinetic and clinical data, as well as pharmacology and toxicology data. The Phase 3 comparative efficacy, safety and immunogenicity study was conducted in adult female patients with HER2-positive early breast cancer.

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.

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. Amgen and Allergan also submitted a Marketing Authorization Application to the European Medicines Agency for ABP 980 earlier this year.

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.

Herceptin® is registered trademark of Genentech.

CONTACT: Amgen, Thousand Oaks
Kristen Davis, 805-447-3008 (media)
Kristen Neese, 805-313-8267 (media)
Arvind Sood, 805-447-1060 (investors)

CONTACT: Allergan plc.
Lisa DeFrancesco, 862-261-7152 (investors)
Mark Marmor, 862-261-7558 (media)



View original content with multimedia:<http://www.prnewswire.com/news-releases/amgen-and-allergan-submit-biosimilar-biologics-license-application-for-abp-980-to-us-food-and-drug-administration-300496238.html>

SOURCE Amgen