



Amgen And Allergan Announce Positive Top-line Results From Phase 3 Study of Biosimilar Candidate ABP 215

September 23, 2015

Study Evaluated Efficacy and Safety of ABP 215 Compared With Bevacizumab in Patients With Advanced Non-small Cell Lung Cancer

Primary Efficacy Analysis Demonstrates Clinical Equivalence; Safety, Immunogenicity Comparable to Bevacizumab

THOUSAND OAKS, Calif. and DUBLIN, Sept. 23, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Allergan plc. (NYSE:AGN) today announced a Phase 3 study of biosimilar candidate ABP 215 met its primary and secondary endpoints. The study evaluated the efficacy and safety of ABP 215 compared with Avastin[®] (bevacizumab) in adult patients with advanced non-squamous non-small cell lung cancer (NSCLC).

The primary endpoint, an assessment of objective response rates (ORR), was within the prespecified margin for ABP 215 compared to bevacizumab, showing clinical equivalence. Safety and immunogenicity of ABP 215 were comparable to bevacizumab. Secondary endpoint results were consistent with the primary finding and included risk difference of ORR, duration of response and progression-free survival (PFS).

ABP 215 is being developed as a biosimilar to bevacizumab, a recombinant immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that binds to vascular endothelial growth factor (VEGF) and inhibits the interaction of VEGF with its receptors, VEGF receptor-1 and VEGF receptor-2, thus inhibiting establishment of new blood vessels necessary for the maintenance and growth of solid tumors.

"Amgen is committed to bringing high-quality, reliably supplied medicines to patients and we're excited to leverage our development and manufacturing capabilities in oncology for our biosimilars. The positive Phase 3 results from ABP 215 study showed clinical equivalence in efficacy, and comparable safety and immunogenicity, to bevacizumab," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Non-small cell lung cancer is the leading cause of cancer death in both men and women in the U.S. and the EU. ABP 215 holds the potential to advance access to treatment options for oncology patients."

"The positive Phase 3 clinical results of ABP 215 mark an important step forward in the development of biosimilar treatment options for patients with advanced non-small cell lung cancer," said David Nicholson, executive vice president and president of Global Research and Development of Allergan. "Allergan is committed to developing biosimilars that provide safe, high-quality and effective therapies in key disease areas for patients."

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 was a randomized, double-blind, active-controlled study (study number 20120265) that evaluated safety and efficacy of ABP 215 compared to bevacizumab in adult patients with advanced non-squamous NSCLC receiving first-line chemotherapy with carboplatin and paclitaxel. There were 642 patients enrolled and randomized (1:1) to receive investigational product (ABP 215 or bevacizumab) at a dose of 15 mg/kg administered as an IV infusion every 3 weeks (Q3W) for up to 6 cycles. Among them, there were 328 patients randomized to the ABP 215 group and 314 patients to the bevacizumab group.

The duration of the treatment included a screening period of up to 4 weeks, followed by up to 6 Q3W treatment cycles and an end of treatment visit 21 days after the last dose of investigational product or study specified chemotherapy. Following the end of treatment visit, patients were followed for disease progression and overall survival (OS) until the end of the clinical study, consent was withdrawn, they were lost to follow-up, death or had proscribed therapy (e.g. commercial bevacizumab, non-study anti-cancer treatment).

Clinical equivalence of the primary endpoint was demonstrated by comparing the confidence interval of the risk ratio in ORR between ABP 215 and bevacizumab to a prespecified margin. Response was determined by independent review based on RECIST criteria.

About Non-Small Cell Lung Cancer

Non-small cell lung cancer (NSCLC) is the leading cause of cancer death in both men and women in the U.S. and the European Union (EU). In the U.S., there were an estimated 226,160 new cases and 160,340 deaths due to NSCLC in 2012, and in the EU there were an estimated 265,600 new cases and 236,000 deaths due to NSCLC in 2006.^{1,2} NSCLC arises from the epithelial cells of the lung of the central bronchi to terminal alveoli. The histological type of NSCLC depends on the cells of origin, most commonly squamous cell carcinoma, large cell carcinoma and adenocarcinoma. Cigarette smoking is the primary risk factor for NSCLC, and other risks include exposure to second hand smoke, family history, radon exposure and exposure to air pollution.³⁻⁶

For patients with metastatic (Stage IV) NSCLC or recurrent NSCLC following surgery and adjuvant chemotherapy, treatment usually consists of combination chemotherapy with a platinum-based regimen, such as cisplatin and gemcitabine or carboplatin and paclitaxel, in repeated 3-week cycles for up to 6 cycles. For patients without squamous cell histology or a recent history of hemoptysis, addition of the anti-VEGF antibody bevacizumab to this regimen improves ORR and prolongs PFS.⁷⁻⁹

Based on these and other data, bevacizumab has been approved in the U.S., EU and elsewhere for first-line treatment in patients with advanced or recurrent non-squamous NSCLC in combination with platinum-based chemotherapy.

About ABP 215

ABP 215 is being developed as a biosimilar to bevacizumab, which is approved in specific combinations in the U.S., EU and other regions for the treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC as well as metastatic carcinoma of the colon or rectum; metastatic renal cell carcinoma; and other region-specific indications.

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 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 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 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 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

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.

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, we 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 Sept. 23, 2015, 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 we and our partners routinely obtain patents for our and 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 savings 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 our ability to pay a dividend or repurchase 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, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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 risks associated with acquisition transactions; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 (such periodic public filings having been filed under the "Actavis plc" name) and from time to time in Allergan's other investor communications. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

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The logo for Amgen, featuring the word "AMGEN" in a bold, blue, sans-serif font. The letters are closely spaced, and a registered trademark symbol (®) is located at the top right of the letter "N".



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