Amgen And Allergan Announce Positive Top-Line Results From Phase 1/ Phase 3 Study Of ABP 798, Biosimilar Candidate To Rituximab

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Study Evaluated Pharmacokinetics, Efficacy and Safety of ABP 798 Compared to Rituximab in Patients With Moderate-to-Severe Rheumatoid Arthritis

THOUSAND OAKS, Calif., Jan. 24, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Allergan plc. (NYSE:AGN) today announced positive top-line results from a Phase 1/ Phase 3 study evaluating the pharmacokinetics, efficacy and safety of biosimilar candidate ABP 798, a biosimilar candidate to RITUXAN® (rituximab), compared to rituximab in patients with moderate-to-severe rheumatoid arthritis. The results demonstrate that the study met its primary endpoint of pharmacokinetic (PK) similarity. Additionally, equivalent efficacy was established and a similar safety profile was demonstrated.

The primary objective of the study was PK similarity comparing ABP 798 to rituximab. The PK endpoints of the study were area under the serum concentration–time curve (AUC) and maximum serum concentration (Cmax), both of which were within the pre-specified equivalence margin. The pre-specified equivalence in efficacy endpoint was measured by Disease Activity Score 28-joint count C reactive protein (DAS28-CRP) change from baseline at week 24. Overall, safety and immunogenicity of ABP 798 were comparable to rituximab. This is the first of two studies intended to form the basis for global regulatory submissions for ABP 798. The second study is being conducted in patients with non-Hodgkin's lymphoma.

"Results from this study show pharmacokinetic and clinical equivalence between ABP 798 and rituximab, further demonstrating Amgen's commitment to providing patients with access to high-quality, biological therapies," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We look forward to continuing to leverage our experience and expertise in biotechnology to bring more biosimilars to patients."

ABP 798 is being developed as a biosimilar candidate to rituximab, a CD20-directed cytolytic antibody that is approved in many regions for the treatment of adult patients with moderate-to-severe rheumatoid arthritis, non-Hodgkin's lymphoma, chronic lymphocytic leukemia, pemphigus vulgaris, granulomatosis with polyangiitis and microscopic polyangiitis.

Amgen has a total of 10 biosimilars in its portfolio, including two that are approved in the United States (U.S.) and three that are approved in the European Union (EU).

About the Study Design
The above referenced Phase 1/ Phase 3 study was a randomized, double-blind trial (study number NCT02792699) that evaluated the PK, efficacy and safety of ABP 798 compared to rituximab in patients with moderate-to-severe rheumatoid arthritis. There were 311 patients enrolled and randomized (1:1:1) to receive either ABP 798, rituximab sourced from the U.S., or rituximab sourced from the EU, administered as an intravenous (IV) infusion at baseline and again at week 24. Among them, 104 patients were randomized to the ABP 798 group, 103 patients were randomized to the rituximab (U.S.) group and 104 patients were randomized to the rituximab (EU) group. The primary PK endpoints of the study were AUC and Cmax. The pre-specified equivalence in efficacy endpoint was measured by DAS28-CRP change from baseline at week 24, and the overall study duration was 48 weeks. Additionally, the study included a single transition for subjects on rituximab (U.S.) to ABP 798.

About Rheumatoid Arthritis
Rheumatoid arthritis (RA) is a chronic inflammatory disease of unknown etiology that affects approximately one percent of the adult population worldwide.[1] RA can cause pain, stiffness, swelling and limitations in the motion and function of multiple joints.[2] In RA, joint damage can significantly worsen over time, especially if left untreated and may impair function.[3]

About ABP 798
ABP 798 is being developed as a biosimilar candidate to rituximab, a CD20-directed cytolytic antibody that is approved in the U.S., EU and other regions for the treatment of adult patients with rheumatoid arthritis, non-Hodgkin's lymphoma, chronic lymphocytic leukemia, pemphigus vulgaris, granulomatosis with polyangiitis and microscopic polyangiitis. The active ingredient of ABP 798 is a CD20-directed cytolytic antibody that has the same amino acid sequence as rituximab. ABP 798 also has the same pharmaceutical dosage form and strength as rituximab.

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 four decades 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
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.

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.

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 current reports on 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, including our devices, 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. 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. 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, including in Puerto Rico, 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. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. 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. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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