Amgen And Allergan Announce Positive Top-Line Results From Comparative Clinical Study Of ABP 798, Biosimilar Candidate To Rituxan® (Rituximab)

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Study Evaluated Efficacy and Safety of ABP 798 Compared to Rituxan in Patients With Non-Hodgkin's Lymphoma

THOUSAND OAKS, Calif., Aug. 22, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Allergan plc. (NYSE:AGN) today announced positive top-line results from a comparative clinical study evaluating the efficacy and safety of ABP 798, a biosimilar candidate to Rituxan® (rituximab), compared to Rituxan in patients with CD20-positive B-cell non-Hodgkin's lymphoma. The primary endpoint, an assessment of overall response rate (ORR) by week 28, was within the prespecified margin for ABP 798 compared to Rituxan, showing clinical equivalence. Safety and immunogenicity of ABP 798 were comparable to Rituxan.

This is the second of two studies intended to support regulatory submissions for ABP 798. The first study was conducted in patients with moderate-to-severe rheumatoid arthritis (RA) and met the primary endpoint of pharmacokinetic similarity. This RA study demonstrated clinical equivalence within the prespecified efficacy margin, and a similar safety and immunogenicity profile.

"Today's results with ABP 798 demonstrate another positive development from Amgen's robust pipeline of biosimilar medicines and we look forward to working with regulatory agencies to bring this treatment to patients," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We continue to leverage our deep expertise and heritage in biologics across innovative and biosimilar medicines as part of our commitment to providing a range of treatment options for patients with the most serious diseases, including cancer."

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

Amgen has a total of 10 biosimilars in its portfolio, including three that are approved in the United States (US).

About the JASMINE Study
The JASMINE study was a randomized, double-blind comparative clinical study (study number NCT02747043) that evaluated the efficacy, safety and immunogenicity of ABP 798 compared to rituximab in patients with non-Hodgkin's lymphoma. There were 256 adult patients enrolled and randomized to receive either ABP 798 or rituximab at a dose of 375 mg/m^2 administered as an intravenous (IV) infusion once weekly for four weeks followed by dosing at weeks 12 and 20. The primary endpoint of the study was risk difference of overall response rate.

About Non-Hodgkin's Lymphoma
Non-Hodgkin's lymphoma is a type of cancer that originates in the lymph system, part of the body's immune system, and occurs when the body produces too many abnormal lymphocytes, a type of white blood cell.[1,2] Non-Hodgkin's lymphoma is one of the most common cancers in the U.S., and about 85 percent of cases originate in B cells.[3,4] There are several subtypes, and follicular lymphoma is one of the most common.[2]

About ABP 798
ABP 798 is being developed as a biosimilar candidate to Rituxan® (rituximab), an anti-CD20- monoclonal antibody that is approved in many regions for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, moderate-to-severe rheumatoid arthritis, pemphigus vulgaris, granulomatosis with polyangiitis and microscopic polyangiitis. The active ingredient of ABP 798 is a monoclonal antibody that has the same amino acid sequence as Rituxan.

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 assumes primary responsibility for developing, manufacturing and initially commercializing the oncology antibody products.

About Amgen Biosimilars
Amgen 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 nearly 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 Oncology
Amgen is searching for and finding answers to incredibly complex questions that will advance care and improve lives for cancer patients and their families. Our research drives us to understand the disease in the context of the patient's life – not just their cancer journey – so they can take control of their lives.

For the last four decades, we have been dedicated to discovering the firsts that matter in oncology and to finding ways to reduce the burden of cancer. Building on our heritage, Amgen continues to advance the largest pipeline in the Company's history, moving with great speed to advance those innovations for the patients who need them.

At Amgen, we are driven by our commitment to transform the lives of cancer patients and keep them at the center of everything we do.

For more information, follow us on www.twitter.com/amgenoncology.

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 global pharmaceutical leader focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world. Allergan markets a portfolio of leading brands and best-in-class products primarily focused on four key therapeutic areas including medical aesthetics, eye care, central nervous system and gastroenterology. As part of its approach to delivering innovation for better patient care, Allergan has built one of the broadest pharmaceutical and device research and development pipelines in the industry.

With colleagues and commercial operations located 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 its 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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its 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 its products and global economic conditions. In addition, sales of Amgen's 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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. Amgen relies on collaborations with third parties for the development of some of its product candidates and for the commercialization and sales of some of its commercial products. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

Allergan plc Forward-Looking Statement
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 on existing trends and information as of the date of this release. 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; the impact of uncertainty around timing of generic entry related to key products, including RESTASIS®, on our financial results; risks associated with divestitures, acquisitions, mergers and joint ventures; risks related to impairments; uncertainty associated with financial projections, projected cost reductions, projected debt reduction, projected synergies, restructurings, increased costs, and adverse tax consequences; 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, 2018 and Allergan's Quarterly Report on Form 10-Q for the period ended June 30, 2019. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

Rituxan® is a registered trademark of Biogen, Inc.

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