AMGEN ANNOUNCES POSITIVE TOP-LINE RESULTS FROM PHASE 3 STUDY OF ABP 959, BIOSIMILAR CANDIDATE TO SOLIRIS® (ECULIZUMAB)

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Study Evaluated the Efficacy, Safety and Immunogenicity of ABP 959 Compared to Eculizumab in Patients With Paroxysmal Nocturnal Hemoglobinuria

THOUSAND OAKS, Calif., Aug. 23, 2022 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced positive top-line results from the DAHLIA study, a randomized, double-blind, active-controlled, two-period crossover Phase 3 study evaluating the efficacy and safety of ABP 959, a biosimilar candidate to SOLIRIS® (eculizumab), compared with SOLIRIS in adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

The study met its primary endpoints, demonstrating no clinically meaningful differences between ABP 959 and SOLIRIS based on the control of intravascular hemolysis as measured by lactate dehydrogenase (LDH) at week 27 for the parallel comparison, and the time-adjusted area under the effect curve (AUEC) of LDH from week 13 to week 27, from week 39 to week 53, and from week 65 to week 79 for the crossover comparison. The safety and immunogenicity profile of ABP 959 was comparable to SOLIRIS.

"Today's positive results with ABP 959 demonstrate similar efficacy, safety and immunogenicity as the reference product, further highlighting Amgen's commitment to providing patients with access to high-quality, biologic therapies," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We look forward to working with regulators to make this potential biosimilar option available to patients."

Detailed results of this study will be presented at a future medical congress and submitted for publication.

ABP 959 is being developed as a biosimilar candidate to SOLIRIS, for the treatment of PNH and other indications. ABP 959 has the same pharmaceutical form, dosage strength, route of administration and dosing regimen as licensed eculizumab in the United States (U.S.) and European Union (EU).

This is not an offer for sale. ABP 959 is currently not available commercially.

Amgen has a total of 11 biosimilars in its portfolio, including five that have been approved in the U.S., three that are approved in the EU, and three in Phase 3 development.

About the DAHLIA Study

This Phase 3 study is a randomized, double-blind, active-controlled, two-period crossover study in adult patients with paroxysmal nocturnal hemoglobinuria (PNH), who have been previously treated with eculizumab for at least six months. Subjects were randomized (1:1) to receive each investigational product (IP) in 1 of 2 sequences, either treatment T followed by treatment R (TR) or treatment R followed by treatment T (RT). Treatment was administered over 2 periods: Period 1 was 52 weeks in duration; Period 2 started at week 53 with a crossover in treatment and was 26 weeks in duration.

Period 1 (week 1 to week 53):
Treatment T: ABP 959 at a dose of 900 mg intravenously (IV) every 14 ± 2 days for 52 weeks
Treatment R: eculizumab at a dose of 900 mg IV every 14 ± 2 days for 52 weeks

Period 2 (week 53 to week 79)
Treatment T: ABP 959 at a dose of 900 mg IV every 14 ± 2 days for 26 weeks
Treatment R: eculizumab at a dose of 900 mg IV every 14 ± 2 days for 26 weeks

About Paroxysmal Nocturnal Hemoglobinuria

Paroxysmal nocturnal hemoglobinuria (PNH) is a rare, life-threatening, bone marrow disorder characterized by intravascular hemolytic anemia, bone marrow failure, and thrombo-embolic episodes, and is associated with a significant increase in mortality, development of arterial and venous thrombo-embolic episodes, visceral organ damage, and rapid deterioration in quality of life.[1,2,3,4] The disease is caused by the expansion of a clone of hematopoietic cells lacking glycosylphosphatidylinositol-anchored membrane proteins, which leads to chronic, complement-mediated intravascular hemolysis.[2]

About ABP 959

ABP 959 is an investigational biosimilar candidate to SOLIRIS® (eculizumab) for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) and other indications. It is a monoclonal antibody that specifically binds to the complement protein C5 and inhibits the progression of both the classical and alternative complement cascades. ABP 959 has the same amino acid sequence as eculizumab and equivalent non-clinical pharmacologic function, based on comprehensive bioanalytical assays.

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 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.

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.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2021, Amgen was named one of the 25 World's Best Workplaces™ by Fortune and Great Place to Work™ and one of the 100 most sustainable companies in the world by Barron's.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

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 any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, or the Teneobio, Inc. acquisition or the recently announced proposed acquisition of ChemoCentryx, Inc., as well as 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, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, 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. 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, 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. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. 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 collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology 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 and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations.

Global economic conditions may magnify certain risks that affect our business. 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.

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. Further, any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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