



AMGEN ANNOUNCES POSITIVE TOP-LINE RESULTS FROM PHASE 3 STUDY OF ABP 654, BIOSIMILAR CANDIDATE TO STELARA® (USTEKINUMAB)

April 18, 2022

Primary Efficacy Analysis Demonstrates no Clinically Meaningful Differences Compared to STELARA

THOUSAND OAKS, Calif., April 18, 2022 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced preliminary results from a Phase 3 study evaluating the efficacy and safety of ABP 654 compared to STELARA® (ustekinumab) in adult patients with moderate to severe plaque psoriasis. The study met the primary efficacy endpoint, demonstrating no clinically meaningful differences between ABP 654 and STELARA.

The primary analysis evaluated the percentage improvement from baseline to week 12 of psoriasis area severity index (PASI), which showed a mean difference of percentage improvement between ABP 654 and STELARA of 0.14, which was within the prespecified margins. The safety profile of ABP 654 was comparable to STELARA.

"Amgen remains committed to providing patients who live with inflammatory diseases access to high-quality biosimilar medicines," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We look forward to continuing to expand our inflammation portfolio to offer patients a variety of treatment options."

ABP 654 is being developed as a biosimilar candidate to STELARA, an approved human interleukin-12 and interleukin-23 antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults and pediatric patients (6 years or older) who are candidates for phototherapy or systemic therapy, active psoriatic arthritis in adults, as well as for adult patients with moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis.

Amgen has a total of 11 biosimilars in its portfolio, including five that have been approved by the U.S. Food and Drug Administration (FDA) and three that are approved in the EU.

About Psoriasis

Psoriasis is a serious, chronic inflammatory disease that causes raised, red, scaly patches to appear on the skin, typically affecting the outside of the elbows, knees, or scalp, though it can appear on any location.¹ Approximately 125 million people worldwide have psoriasis, including around 14 million people in Europe and more than 7.5 million people in the United States.^{2,3} About 80% of those patients have plaque psoriasis.⁴

About the ABP 654 Comparative Clinical Study (20190232)

The Phase 3 study was a multicenter, randomized, double-blinded, comparative clinical study (study number 04607980) that evaluated the efficacy and safety of ABP 654 compared to STELARA® (ustekinumab) in adult patients with moderate to severe plaque psoriasis. There were 563 patients randomized, with 281 patients in the ABP 654 group and 282 patients in the ustekinumab group.

About ABP 654

ABP 654 is being developed as a biosimilar candidate to STELARA® (ustekinumab), an approved human interleukin-12 and interleukin-23 antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults and pediatric patients (6 years or older) who are candidates for phototherapy or systemic therapy, active psoriatic arthritis in adults, as well as for adult patients with moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis. ABP 654 has the same pharmaceutical form, dosage strength, route of administration and dosing regimen as United States-licensed and European Union (EU)-approved ustekinumab.

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 over 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, 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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