



## FDA Accepts Amgen's Biosimilar Biologics License Application For ABP 501

January 25, 2016

THOUSAND OAKS, Calif., Jan. 25, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review Amgen's Biologics License Application (BLA) for ABP 501, a biosimilar candidate to Humira® (adalimumab).

"If approved, we believe ABP 501 could serve as an important additional approved therapeutic option for patients with chronic inflammatory conditions," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to potentially expanding our robust portfolio of approved products, and further demonstrating our continued commitment to delivering high-quality medicines to patients worldwide."

The BLA, submitted on Nov. 25, 2015, is based on analytical, clinical and pharmacokinetic data. Phase 3 comparative efficacy and safety studies were conducted in both moderate-to-severe plaque psoriasis and moderate-to-severe rheumatoid arthritis. The Phase 3 studies met their primary endpoints showing clinical equivalence to adalimumab. Safety and immunogenicity of ABP 501 were also comparable to adalimumab. Data to support the transition of adalimumab patients to ABP 501 are included in the submission.

The FDA has set a Biosimilar User Fee Act (BsUFA) target action date of Sept. 25, 2016, for ABP 501.

### About ABP 501

ABP 501 is a biosimilar candidate to adalimumab, an anti-TNF- $\alpha$  monoclonal antibody, which is approved in many regions for the treatment of several inflammatory diseases. The active ingredient of ABP 501 is an anti-TNF- $\alpha$  monoclonal antibody that has the same amino acid sequence as adalimumab. ABP 501 has the same pharmaceutical dosage form and strength as adalimumab (U.S.) and adalimumab (EU).

### 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 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](http://www.amgenbiosimilars.com) and follow us on [www.twitter.com/amgenbiosim](http://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](http://www.amgen.com) and follow us on [www.twitter.com/amgen](http://www.twitter.com/amgen).

### Forward-Looking Statements

This news release contains forward-looking statements that are based on management's current expectations and beliefs 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, including Amgen'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'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 Jan. 25, 2016 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 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 products 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 are affected by the reimbursement policies imposed by third-party payors, 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 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 and there can be no guarantee of our 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. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our ongoing restructuring plan. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our 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 (FDA) or the European Medicines Agency (EMA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/fda-accepts-amgens-biosimilar-biologics-license-application-for-abp-501-300209337.html>

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