Amgen Presents Detailed Results From Phase 3 Study Demonstrating Clinical Equivalence Of Biosimilar Candidate ABP 501 With Adalimumab

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First Completed Phase 3 Study of Adalimumab Biosimilar in the Treatment of Patients With Moderate-to-Severe Rheumatoid Arthritis

THOUSAND OAKS, Calif., Nov. 9, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today presented detailed findings from a head-to-head Phase 3 study comparing the safety, efficacy and immunogenicity of biosimilar candidate ABP 501 with adalimumab in patients with moderate-to-severe rheumatoid arthritis. The results were presented today in an oral presentation at the 2015 American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) Annual Meeting in San Francisco.

The study met the primary endpoint, which was achievement of ACR20 (20 percent or greater improvement in ACR assessment) at week 24. At week 24, 74.6 percent of patients in the ABP 501 group and 72.4 percent in the adalimumab group met the ACR20 response criteria. The risk ratio of ACR20 was 1.039 with the two-sided 90 percent CI of 0.954–1.133, which fell within the predefined equivalence margin.

"Demonstrating biosimilarity is scientifically complex, but Amgen's 35 years of proven biologic R&D experience is facilitating the advancement of exciting programs like ABP 501," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Our long-term commitment to advancing care in inflammation is as strong as ever, with a portfolio of novel and biosimilar compounds that have the potential to benefit patients worldwide."

ABP 501 is being developed as a biosimilar candidate to adalimumab, an anti-TNF-α monoclonal antibody, which is approved in many countries for the treatment of inflammatory diseases, including moderate-to-severe rheumatoid arthritis, moderate-to-severe plaque psoriasis, moderate-to-severe polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, moderate-to-severe Crohn's disease and moderate-to-severe ulcerative colitis.

Secondary endpoints included the achievement of ACR50 and ACR70 (a 50 or 70 percent improvement in ACR assessment) within the predefined equivalence margin. At week 24, patients treated with ABP 501 compared with those treated with adalimumab achieved ACR50 (49.2 percent vs. 52.0 percent) and ACR70 (26.0 percent vs. 22.9 percent), respectively. Additionally, the secondary endpoint of a difference in change from baseline of DAS28-CRP (Disease Activity Score examines 28 joints in the body as measured by C reactive protein in the blood) over the entire study was also achieved. The difference in mean change from baseline in DAS28-CRP between ABP 501 and adalimumab was –0.01 (90 percent CI, –0.18 to 0.17) at week 24.

The incidence of treatment-emergent adverse events (TEAEs) was 50 percent for ABP 501 and 55 percent for adalimumab. The most frequently reported TEAEs (for ABP 501 and adalimumab, respectively) were nasopharyngitis (6.4 percent vs. 7.3 percent), headache (4.5 percent vs. 4.2 percent), arthralgia (3.0 percent vs. 3.4 percent), cough (2.7 percent vs. 3.1 percent) and upper respiratory tract infection (1.5 percent vs. 3.8 percent). Serious adverse events (3.8 percent vs. 5.0 percent) and serious infections (0.8 percent vs. 1.1 percent) were reported in patients treated with ABP 501 and adalimumab, respectively. By the end of week 24, binding antibodies (38.3 percent vs. 38.2 percent) and neutralizing antibodies were identified (9.1 percent vs. 11.1 percent) in patients treated with ABP 501 and adalimumab, respectively.

Study Design

This randomized, double-blind, active-controlled study (study number 20120262) evaluated safety, efficacy and immunogenicity of ABP 501 compared to adalimumab in adult patients with moderate-to-severe rheumatoid arthritis who had an inadequate response to methotrexate. The study consisted of a screening period of four weeks and a treatment period of 22 weeks. Patients were randomized to receive either 40 mg ABP 501 subcutaneous injection (SC) every two weeks (n=264) or 40 mg SC adalimumab every two weeks (n=262) until week 22. The study completed at week 24, followed by a safety follow-up period through to week 26.

About Rheumatoid Arthritis

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

About ABP 501

ABP 501 is being developed as a biosimilar candidate for adalimumab, an anti-TNF-α 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-α monoclonal antibody that has the same amino acid sequence as adalimumab. ABP 501 has the same pharmaceutical dosage form and strength as adalimumab.

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 suffering from 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.

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 and follow us on www.twitter.com/amgen.

Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen, we or us) 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 Inc., including Amgen Inc.'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 Inc.'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 Nov. 9, 2015, 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 and our partners 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 product 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 (including products of our wholly-owned subsidiaries) are affected by the 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 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 and our partners routinely obtain patents for our and their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' 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. Cost savings initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plans. 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 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, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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[1] Arthritis Foundation. Rheumatoid arthritis symptoms. http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/symptoms.php
[2] Arthritis Foundation. Joint deformities in rheumatoid arthritis. http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/articles/ra-deformities.php

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/amgen-presents-detailed-results-from-phase-3-study-demonstrating-clinical-equivalence-of-biosimilar-candidate-abp-501-with-adalimumab-300175207.html

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