Amgen Submits Biologics License Application for ABP 710 (Biosimilar Infliximab) To US Food And Drug Administration

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Filing for ABP 710, a Biosimilar Candidate to Infliximab, Supported by Phase 3 Study in Patients With Moderate-to-Severe Rheumatoid Arthritis

THOUSAND OAKS, Calif., Dec. 17, 2018 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ABP 710, a biosimilar candidate to REMICADE® (infliximab).

"At Amgen, we have spent nearly four decades developing, manufacturing and producing transformative medicines. We're leveraging our deep expertise and heritage in biologics to produce a portfolio of biosimilars to serve patients with the most complex diseases," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We're committed to providing patients with serious illnesses access to high-quality biological therapies and look forward to working with the FDA to potentially bring ABP 710 to market."

ABP 710 is being investigated as a biosimilar candidate to infliximab, an anti-tumor necrosis factor alpha (anti-TNF) monoclonal antibody, which is approved in many regions for the treatment of moderate to severe rheumatoid arthritis, chronic severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, psoriatic arthritis and ankylosing spondylitis.

The BLA submission includes analytical, pharmacokinetic and clinical data, as well as pharmacology and toxicology data. The Phase 3 comparative efficacy, safety and immunogenicity study was conducted in patients with moderate-to-severe rheumatoid arthritis and confirmed no clinically meaningful differences between ABP 710 and infliximab.

Amgen has a total of 10 biosimilars in its portfolio, including two that are approved in the U.S. and three that are approved in the European Union (EU).

About ABP 710
ABP 710 is being developed as a biosimilar candidate for infliximab, an anti-tumor necrosis factor alpha (anti-TNF) monoclonal antibody, which is approved in U.S., EU and other regions for the treatment of conditions including moderate to severe rheumatoid arthritis, chronic severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, psoriatic arthritis, ankylosing spondylitis. The active ingredient of ABP 710 is an anti-TNF monoclonal antibody that has the same amino acid sequence as infliximab. ABP 710 has the same pharmaceutical dosage form and strength as infliximab.

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 will help to maintain Amgen's commitment to connect patients with vital medicines, and Amgen is well positioned to leverage its 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
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 the world's largest independent biotechnology company, 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. 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 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. 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. 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 acquire other companies or products and to integrate the operations of companies 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 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.

CONTACT: Amgen, Thousand Oaks
Kelley Davenport, 202-585-9637 (media)
Kristen Davis, 805-447-3008 (media)
Arvind Sood, 805-447-1060 (investors)

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