Amgen Announces Participation Of Systemic Lupus Erythematosus (SLE) Adaptive Clinical Trial In The FDA Complex Innovative Trial Designs (CID) Pilot Program

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Amgen and FDA Collaborate on Novel Clinical Trial Design to Advance Development of Potential Treatment for Patients With Uncontrolled SLE

THOUSAND OAKS, Calif., Oct. 27, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it has completed trial design discussions through two Complex Innovative Trial Designs (CID) Pilot Program meetings with the U.S. Food and Drug Administration (FDA) for its planned Phase 2 efficacy and safety trial for efavaleukin alfa (formerly known as AMG 592), an investigational candidate for Systemic Lupus Erythematosus (SLE) treatment. The CID Pilot Program aims to modernize drug development, improve efficiency, and promote innovation. The efavaleukin alfa participation in the CID Pilot Program is based on an innovative adaptive clinical trial design developed to foster the acceleration of a potential therapeutic option that could benefit patients living with SLE.

"Systemic Lupus Erythematosus is an area with significant need for new therapies for those living with the condition, but one that has been challenging to address given the complexity of this autoimmune disease," said Rob Lenz, M.D., Ph.D., senior vice president, Global Development at Amgen. "Our partnership with the FDA on the CID Pilot Program should drive the development of a new treatment for lupus to address unmet need for patients."

"Amgen welcomes the opportunity to partner with the FDA through participation in the CID Pilot Program, which intends to advocate innovative clinical trial designs, as well as provide the FDA an opportunity to communicate these advances publicly," said Steven Galson, M.D., senior vice president, Global Regulatory Affairs and Strategy at Amgen. "We appreciate the FDA's efforts, significant contributions and feedback provided throughout the Pilot process."

The CID Pilot Program fulfills a performance goal agreed to under the Prescription Drug User Fee Act (PDUFA) VI, aiming to facilitate and advance the use of novel clinical trial designs that support the development and regulatory review of new therapeutics. Designs under the CID umbrella include, but are not limited to, complex adaptive, Bayesian, and other novel clinical trial designs which often require simulations to determine the statistical properties of the trial. The FDA considers several eligibility factors when selecting qualifying programs, including the level of innovation of the trial design, and the therapeutic need.

About Systemic Lupus Erythematosus
Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease that can impact multiple organ systems leading to fatigue, kidney failure, arthritis, rash and cardiovascular disease. While SLE disease activity is variable, most patients continue to experience periods of increased symptoms or flares which are associated with permanent organ damage and is associated with increased risk of death due to cardiovascular disease, infection and renal disease. Current treatments for SLE aim to control the symptoms by suppressing the immune response.

Efavaleukin alfa
Efavaleukin alfa is an IL-2 mutein Fc fusion protein. It is being investigated for the treatment of inflammatory diseases, including Systemic Lupus Erythematosus.

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.

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. or any collaboration or potential collaboration in pursuit of therapeutic antibodies against COVID-19 (including statements regarding such collaboration's, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 or antibodies against targets other than the SARS-CoV-2 receptor binding domain, and/or to produce any such antibodies to potentially prevent or treat COVID-19), or the Otezla® (apremilast) acquisition (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), 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, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, 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 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.

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