

Amgen And AstraZeneca To Present Results From Phase 3 AMAGINE-1™ Study Evaluating Brodalumab In Patients With Moderate-To-Severe Plaque Psoriasis

December 11, 2014

First Presentation of Phase 3 Data From Brodalumab Psoriasis Program

THOUSAND OAKS, Calif. and LONDON, Dec. 11, 2014 /PRNewswire/ -- Amgen (NASDAQ: AMGN) and AstraZeneca (NYSE: AZN) today announced that additional results from AMAGINE-1TM, a pivotal, multi-arm Phase 3 trial evaluating two doses of brodalumab in patients with moderate-to-severe plaque psoriasis will be presented at the Psoriasis: From Gene to Clinic International Congress in London on Saturday, Dec. 13, 2014, at 11:20 a.m. GMT (Abstract FC30). Brodalumab is the only investigational treatment in development that binds to the interleukin-17 (IL-17) receptor and inhibits inflammatory signaling by blocking the binding of several IL-17 cytokines (A, F and A/F) to the receptor. The IL-17 receptor and cytokine family play a central role in the development and clinical manifestations of plaque psoriasis.

"We are excited to present additional data from AMAGINE-1, which provide further insight into brodalumab's potential role in addressing the unmet needs of patients living with psoriasis," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We continue to be encouraged by the emerging data from this program and look forward to initiating global regulatory filings in 2015."

The AMAGINE-1 trial assessed the safety and efficacy of brodalumab given every two weeks via subcutaneous injection at two doses (140 mg or 210 mg) compared with placebo after 12 weeks of treatment in patients with moderate-to-severe plaque psoriasis. Another purpose of the study was to assess safety and efficacy when patients treated with brodalumab, who responded to treatment, continued receiving brodalumab compared to patients who had treatment withdrawn and began receiving placebo. Data being presented include results through week 52.

The AMAGINE program comprises three pivotal Phase 3 studies designed to assess the efficacy and safety of brodalumab in more than 4,200 patients with moderate-to-severe plaque psoriasis. Positive top-line results from AMAGINE-1 were released in May 2014. Positive top-line results from AMAGINE-2TM and AMAGINE-3TM, comparing brodalumab with Stelara[®] (ustekinumab) and placebo, were announced in November 2014. AMAGINE-2 and AMAGINE-3 are identical in design.

About Brodalumab (AMG 827)

Brodalumab is a novel human monoclonal antibody that binds to the interleukin-17 (IL-17) receptor and inhibits inflammatory signaling by blocking the binding of several IL-17 ligands to the receptor. By stopping IL-17 ligands from activating the receptor, brodalumab prevents the body from receiving signals that may lead to inflammation. The IL-17 pathway plays a central role in inducing and promoting inflammatory disease processes. In addition to moderate-to-severe plaque psoriasis (Phase 3), brodalumab is currently being investigated for the treatment of psoriatic arthritis (Phase 3) and asthma (Phase 2).

About the Amgen and AstraZeneca Collaboration

In April 2012, Amgen and AstraZeneca formed a collaboration to jointly develop and commercialize five monoclonal antibodies from Amgen's clinical inflammation portfolio. With oversight from joint governing bodies, Amgen leads clinical development and commercialization for brodalumab (Phase 3 for moderate-to-severe plaque psoriasis and psoriatic arthritis, Phase 2 for asthma) and AMG 557/MEDI5872 (Phase 1b for autoimmune diseases, such as systemic lupus erythematosus). AstraZeneca, through its biologics arm MedImmune, leads clinical development and commercialization for MEDI7183/AMG 181 (Phase 2 for ulcerative colitis and Crohn's disease), MEDI2070/AMG 139 (Phase 2 for Crohn's disease) and MEDI9929/AMG 157 (Phase 2 for asthma).

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.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

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 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, we are providing this information as of Dec. 11, 2014, and expressly disclaim 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.

Stelara® is a registered trademark of Janssen Biotech, Inc.

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References:

1. Miossec P, Korn T, Kuchroo VK. Interleukin-17 and Type 17 Helper T Cells. The New England Journal of Medicine. 2009; 361: 888-98.





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