Amgen And AstraZeneca Announce Positive Results From Phase 3 Study Of Brodalumab (AMG 827) In Patients With Moderate-to-Severe Plaque Psoriasis

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Study Evaluating Novel Investigational IL-17 Receptor Antibody Meets All Primary and Secondary Endpoints

THOUSAND OAKS, Calif. and LONDON, May 9, 2014 /PRNewswire/ -- Amgen (NASDAQ: AMGN) and AstraZeneca today announced that the Phase 3 AMAGINE-1™ study evaluating brodalumab in patients with moderate-to-severe plaque psoriasis met all primary and secondary endpoints for both evaluated doses. 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 ligands to the receptor. Primary endpoints were patients achieving at least a 75 percent improvement from baseline in disease severity at week 12, as measured by the Psoriasis Area Severity Index (PASI 75), and patients achieving clear or almost clear skin at week 12 according to the static Physician Global Assessment (sPGA 0 or 1).

A significantly higher proportion of patients treated with brodalumab achieved a PASI 75 response (primary endpoint), as well as PASI 90 and PASI 100 responses at week 12 (secondary endpoints) compared to placebo. Results showed that 83.3 percent of patients in the 210 mg group and 60.3 percent of patients in the 140 mg group achieved PASI 75 responses compared to placebo (2.7 percent). Results also showed that 70.3 percent of patients in the 210 mg group and 42.5 percent of patients in the 140 mg group achieved PASI 90 responses compared to placebo (0.9 percent). Further, 41.9 percent of patients in the 210 mg group and 23.3 percent of patients in the 140 mg group achieved PASI 100 responses compared to placebo (0.5 percent). Of the 661 patients enrolled in this study, 46 percent reported prior biologic use and 28.7 percent weighed more than 100 kilograms (kg) at baseline (mean weight for the study population was 90.8 kg).

A PASI score is a measure of psoriatic plaque redness, scaling and thickness and the extent of involvement in each region of the body. Treatment efficacy is often measured by the reduction of PASI from baseline (i.e., a 75 percent reduction is known as PASI 75, a 90 percent reduction is known as PASI 90 and PASI 100 is total clearance of skin disease).

The most common adverse events that occurred during the placebo-controlled period in the brodalumab group (more than 5 percent of participants) were nasopharyngitis, upper respiratory tract infection and headache. Serious adverse events occurred in 1.8 percent of patients in the 210 mg group and 2.7 percent of patients in the 140 mg group compared to 1.4 percent for placebo during the placebo-controlled period.

"Data from the AMAGINE-1 study suggest that brodalumab may offer a new level of efficacy for patients with moderate-to-severe plaque psoriasis, a disease that affects more than 100 million people globally," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "This is the first read-out from our Phase 3 psoriasis clinical program and we look forward to obtaining additional Phase 3 data from our two head-to-head studies versus ustekinumab later this year."

Psoriasis is a non-contagious chronic disease in which the immune system causes skin cells to grow at an accelerated rate. Instead of being shed, skin cells pile up, causing painful and itchy, red, scaly patches.

"Moderate-to-severe plaque psoriasis is a serious disease, and despite available treatments, there is still a significant need for more effective therapies," said Briggs W. Morrison, M.D., executive vice president of Global Medicines Development at AstraZeneca. "We are encouraged by brodalumab's emerging profile and look forward to presenting the full data in the appropriate scientific forum."

AMAGINE-1 is one of three Phase 3 studies designed to assess the efficacy and safety of brodalumab in patients with moderate-to-severe plaque psoriasis. AMAGINE-2 and AMAGINE-3 are designed to evaluate the efficacy and safety of induction and maintenance regimens of brodalumab at different dose schedules in patients with moderate-to-severe plaque psoriasis compared to ustekinumab and placebo.

AMAGINE-1 Study Design

AMAGINE-1 assessed the safety and efficacy of brodalumab given every two weeks via subcutaneous injection at two doses (140 mg or 210 mg) compared to placebo 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, began receiving placebo compared to the patients who continued receiving brodalumab.

The Phase 3 study began with a 12-week, double-blind, placebo-controlled induction phase. During this phase, patients were randomized in a 1:1:1 ratio to receive 210 mg of brodalumab, 140 mg of brodalumab or placebo every two weeks.

At week 12, patients originally randomized to receive treatment with brodalumab who achieved clear or almost clear skin according to their sPGA (0 or 1) were rerandomized 1:1 to receive placebo or continued treatment with brodalumab at the current dose. Rerandomized patients losing disease control were treated with their original brodalumab dose. All patients originally randomized to placebo and any patient not qualifying for rerandomization (sPGA > 1) received 210 mg of brodalumab every two weeks.

sPGA is a physician's rating of psoriasis severity at a given point in time based on plaque, scaling and redness. A physician can rate a patient's psoriasis as clear (0), almost clear (1), mild (2), moderate (3), severe (4) or very severe (5).

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 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.

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) 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 Amgen's business. Unless otherwise noted, Amgen is providing this information as of May 9, 2014 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 Amgen projects. 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 Amgen and its partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development.

In addition, sales of Amgen's products (including products of Amgen's 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 Amgen's products. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. In addition, while Amgen and its partners routinely obtain patents for their products and technology, the protection of Amgen's products offered by patents and patent applications may be challenged, invalidated or circumvented by its competitors and there can be no guarantee of Amgen's or its partners' ability to obtain or maintain patent protection for Amgen's products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations. Amgen's efforts to integrate the operations of companies it has acquired may not be successful.

The scientific information discussed in this news release relating to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA) , and no conclusions can or should be drawn regarding the safety or effectiveness

of the product candidates.

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