The New England Journal Of Medicine Publishes Positive Proof-Of-Concept Data For New Asthma Treatment

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Early Data Demonstrate Anti-TSLP Therapy Reduces Early and Late Asthmatic Responses and Several Key Inflammatory Markers

THOUSAND OAKS, Calif., May 20, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that *The New England Journal of Medicine* (NEJM) published positive results from a Phase 1 study adding to the growing body of evidence that inhibiting thymic stromal lymphopoietin (TSLP) could be beneficial in the treatment of asthma. TSLP is a cytokine thought to be a key driver of allergic inflammation. These are the first clinical data to be reported for an anti-TSLP therapy. The results were also presented today at the American Thoracic Society 2014 international conference taking place in San Diego.

Results from the 31-patient study showed treatment for 12 weeks with AMG 157, a monoclonal antibody that inhibits the activity of TSLP, resulted in statistically significant reductions in early asthmatic responses (EAR) and late asthmatic responses (LAR) in the airways following allergen challenges in patients with allergic (atopic) asthma. The data also showed statistically significant decreases in baseline markers of inflammation in the airways. Overall, adverse events were similar across treatment and placebo groups (15 events in the treatment arm versus 12 events in the placebo arm), with no serious adverse events occurring in the study.

"While these data are very early, they help to confirm our belief that TSLP is a critical early mediator that may be responsible for persisting airway inflammation and triggering the inflammatory response to allergens in allergic asthmatic patients," said Paul M. O'Byrne, MB, FRCPC, FRSC, executive director of the Firestone Institute for Respiratory Health, St. Joseph's Healthcare, Hamilton, Ontario, Canada. "These results form the basis for further development of this compound."

AMG 157 is a monoclonal immunoglobulin IgG2λ that binds to and inhibits TSLP from interacting with its receptor. TSLP is a cytokine that is believed to play a critical role in the start of the allergic cascade, specifically the inflammatory response, and is generated by lung tissue when an allergen is introduced. Studies have also shown higher amounts of TSLP were produced in the lung tissue of individuals with asthma compared to healthy individuals, and the TSLP gene has been associated with both childhood and adult allergic asthma.

"Understanding the underlying biology of disease is critically important to continuing to discover novel treatments for patients suffering from a variety of diseases," said Brian Kotzin, M.D., vice president of Global Development at Amgen. "These data give us insight into the importance of TSLP as a mediator of asthmatic response and the ability to inhibit inflammation in asthma."

MEDI9929/AMG 157[1] is being jointly developed by Amgen and AstraZeneca, with its global biologics research and development arm MedImmune. MEDI9929/AMG 157 is currently in Phase 2 development for the treatment of asthma. Click here for more information.

"We are encouraged by these early results and look forward to leading further development of this promising new biologic in partnership with Amgen," said Bing Yao, Ph.D., senior vice president and head of MedImmune's Respiratory, Inflammation and Autoimmunity Innovative Medicines Unit. "The goal of the Phase 2 study is to understand if this approach could provide benefit for patients with severe asthma."

Study Design

The double-blind, placebo-controlled parallel-group study was conducted as a proof-of-concept study to determine whether treatment with AMG 157 prevents allergen-induced airway responses in patients with allergic asthma. Thirty-one participants who developed EAR and LAR were enrolled and randomized to AMG 157 (n=16) or placebo (n=15). Participants received three doses of AMG 157 (700 mg intravenously) or placebo, four weeks apart. Allergen challenges were conducted on days -14, 42 and 84.

Detailed results from this trial were published in NEJM and can be viewed here.

About Asthma

An estimated 300 million people worldwide have asthma[2], a chronic inflammatory disease of the airways, characterized by recurrent episodes of wheezing, breathlessness, chest tightness and cough. Approximately 70 percent of asthma patients[3] also have allergies. Allergic asthma is caused in part by a genetic tendency to develop allergic diseases, typically associated with heightened immune responses to common allergens, especially inhaled allergens and food allergens. Allergen inhalation by atopic asthmatics causes symptoms including reversible airflow obstruction, airway hyperresponsiveness, and airway inflammation.

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.

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 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 May 20, 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 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 Amgen and its partners routinely obtain patents for 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.

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 (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

References

[1] As part of the collaboration agreement, the compound reference number has been changed from AMG 157 to MEDI9929/AMG 157. Phase 2 clinical studies are referenced on clinicaltrials.gov under MEDI9929 or AMG 157.

[2] Centers for Disease Control and Prevention, Vital Signs, May 2011.

[3] World Health Organization. *Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach*, 2007.

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