Amgen Joins The National Cancer Institute And Research Partners To Help Accelerate Development Of Personalized Treatment Approaches For Squamous Cell Lung Cancer

June 16, 2014

Lung-MAP Trial Will Test Five Investigational Approaches, Including Amgen's Rilotumumab, an Investigational Fully Human Monoclonal Antibody

THOUSAND OAKS, Calif., June 16, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) announced today that it will collaborate with the National Cancer Institute (NCI), part of the National Institutes of Health, and other public and private sector partners on the Lung Master Protocol (Lung-MAP), a groundbreaking new clinical trial program that will use biomarker-driven research and genomic profiling to match squamous cell lung cancer patients to investigational treatments based on their individual cancer profiles. Lung-MAP is the first trial of its kind to study a large number of rare lung cancer subsets under one trial protocol.

Approximately 500 to 1,000 patients will be screened each year for more than 200 cancer-related genes, and the screenings will inform trial arm selection. Five investigational drugs have been selected for inclusion in the initial trial, including Amgen's rilotumumab, an investigational fully human monoclonal antibody designed to inhibit cancer cell growth and migration.

"Amgen has been at the forefront of biomarker research in an effort to help the medical community understand the different mechanisms of cancer progression and ensure that patients receive treatments that will provide the greatest benefit," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "This latest collaboration can significantly speed our understanding of targeted approaches for this complex and underserved form of lung cancer, while demonstrating how genomic testing can drive the evolution of clinical trial design. It may ultimately tell us more about how best to match patients to the right treatments."

In the U.S., lung cancer is the leading cause of cancer death and the second most common cancer.[1] Approximately 25-30 percent of non-small cell lung cancers, the most common form of lung cancer, are squamous cell carcinomas.[2] However, there are limited treatment options available for squamous cell carcinomas and development of treatments has been further complicated by the number of potential genetic mutations associated with this form of cancer. Research has demonstrated that squamous cell lung cancer has more than double the genetic mutations compared to other forms of cancer.[3]

About Lung-MAP
Lung-MAP is a biomarker-driven, multi-drug, multi-arm Phase 2/3 registration clinical trial for patients with squamous cell lung cancer. The trial will evaluate five investigational compounds intended to treat squamous cell lung cancer and use genomic sequencing to assign enrolled patients to the treatment arms most likely to provide benefit. Patients will then be randomized into one of five sub-studies where they will receive either standard of care (docetaxel or erlotinib) or biomarker-driven targeted therapy with an investigational agent. Each of these sub-studies will be independently powered for overall survival (OS) with an interim analysis for progression-free survival (PFS) to determine whether to proceed from Phase 2 into Phase 3.[4,5]

Lung-MAP is being conducted in collaboration with the NCI, part of the National Institutes of Health, SWOG Cancer Research, Friends of Cancer Research (Friends), the Foundation for the National Institutes of Health (FNIH), five pharmaceutical companies (Amgen, Genentech, Pfizer, AstraZeneca, and MedImmune, AstraZeneca's global biologics R&D arm), and Foundation Medicine.

About Rilotumumab
Rilotumumab is an investigational fully human monoclonal antibody designed to inhibit the hepatocyte growth factor/scatter factor (HGF/SF):MET pathway, which has the potential to reduce cell proliferation, impair survival signals, and prevent the migration and invasion of tumor cells. In addition to evaluating the potential of rilotumumab in the treatment of squamous cell carcinomas in lung cancer as part of the Lung-MAP clinical trial program, the compound is also currently undergoing Phase 3 evaluation in advanced gastric/gastroesophageal junction cancer.

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 June 16, 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.

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