Amgen's Talimogene Laherparepvec Reduced Size Of Melanoma Tumors In New Phase 3 Retrospective Analysis

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Data Showed Tumor Shrinkage in Both Injected and Metastasized Tumors
Results from Amgen's Investigational Oncolytic Immunotherapy Presented Today at the Society for Surgical Oncology Congress in Phoenix

THOUSAND OAKS, Calif., March 14, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced findings from a pre-specified retrospective analysis of patients with metastatic melanoma that showed talimogene laherparepvec reduced the size of injected tumors and also non-injected tumors that had metastasized to other parts of the body. The analysis recorded tumor-level responses from a pivotal Phase 3 study evaluating talimogene laherparepvec in patients with injectable unresected stage IIIB, IIIC or IV melanoma compared to granulocyte-macrophage colony-stimulating factor (GM-CSF). Full results were presented today during an oral session at the Society of Surgical Oncology (SSO) 67th Annual Cancer Symposium in Phoenix.

Talimogene laherparepvec is an investigational oncolytic immunotherapy designed to selectively replicate in tumor tissue and to initiate a systemic anti-tumor immune response.

Of the 295 patients treated with talimogene laherparepvec, almost 4,000 tumor lesions were tracked for this analysis. Half of these lesions were injected with talimogene laherparepvec at least once, while the rest were not injected, including visceral tumor lesions (tumors involving solid organs such as the lungs and liver). The results showed a 50 percent or greater reduction in tumor size in 64 percent of injected tumors. In addition, one-third of uninjected non-visceral tumors, and 15 percent of visceral tumors were also reduced by at least 50 percent. There were 35 melanoma-related surgeries performed during this trial of which 30 percent successfully removed all residual disease.

The most frequently observed adverse events in the Phase 3 study were fatigue, chills and pyrexia. The most common serious adverse events include disease progression in both groups, and cellulitis and pyrexia in the talimogene laherparepvec group. Serious adverse events occurred in 26 percent of talimogene laherparepvec patients and 13 percent of GM-CSF patients. Immune-mediated events were reported infrequently.

"These data add to the body of evidence supporting talimogene laherparepvec's local and distant effect, and its potential ability to stimulate a systemic anti-tumor immune response," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Melanoma remains a devastating and difficult-to-treat disease, and talimogene laherparepvec continues to demonstrate encouraging results in this setting."

About Talimogene Laherparepvec
Talimogene laherparepvec is an investigational oncolytic immunotherapy designed to selectively replicate in tumor tissue and to initiate a systemic anti-tumor immune response. Talimogene laherparepvec is injected directly into tumor tissue and is intended to replicate preferentially in tumor cells causing lytic cell death and releasing an array of tumor-derived antigens. Talimogene laherparepvec is also engineered to express granulocyte-macrophage colony-stimulating factor (GM-CSF), a white blood cell growth factor, which can help to activate the immune system. The aim of this combination of actions is to initiate a systemic anti-tumor immune response that targets tumor cells throughout the body.

About Melanoma
Melanoma is a type of skin cancer that is characterized by the uncontrolled growth of melanocytes, which are the cells responsible for providing the pigment to skin.[1] Melanoma is the most aggressive and serious form of skin cancer. Currently, 132,000 melanoma cases occur globally each year.[2] In the U.S., while melanoma accounts for less than 5 percent of skin cancer cases, it causes the most skin cancer deaths.[2] The number of new cases of melanoma in the U.S. has been increasing for the last 30 years.[2]

Melanoma is considered to be advanced when it has spread, or metastasized, from the origin site to deeper parts of the skin or other organs such as the lymph nodes, lungs or other parts of the body distant from the primary tumor site.[3]

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 March 14, 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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