Pivotal Study Results Published in Journal of Clinical Oncology Showed Talimogene Laherparepvec Improved Durable Response Rates in Patients With Metastatic Melanoma

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Talimogene Laherparepvec First Oncolytic Immunotherapy to Demonstrate Therapeutic Benefit for Patients With Advanced Melanoma

Metastatic Melanoma Most Aggressive Form of Skin Cancer

THOUSAND OAKS, Calif., May 26, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced the publication of primary results from the Phase 3 OPTiM study in the *Journal of Clinical Oncology* (*JCO*). The data published in *JCO*, which were previously presented at the Annual Meetings of the American Society of Clinical Oncology (ASCO) in 2013 and 2014, demonstrated a significantly higher durable response rate (DRR) in patients with unresected stage IIIB, IIIC or IV metastatic melanoma receiving the investigational oncolytic immunotherapy talimogene laherparepvec compared to those who received granulocyte-macrophage colony-stimulating factor (GM-CSF). Results showed that the primary endpoint of DRR was met, however the secondary endpoint of overall survival (OS) was not met, although there was a strong trend in favor of talimogene laherparepvec.

"Oncolytic virus immunotherapy may become a new approach to melanoma treatment, and the OPTiM study demonstrated durable responses in talimogene laherparepvec treated patients with metastatic melanoma," said lead investigator Howard L. Kaufman, M.D., associate director for Clinical Science at the Rutgers Cancer Institute of New Jersey and president of the Society for Immunotherapy of Cancer. "Talimogene laherparepvec may offer a potential new treatment option for patients with this aggressive form of skin cancer."

A DRR measures the number of patients who had a complete response or partial response within the first 12 months of treatment and maintained the response continuously for at least 6 months.

The most frequent adverse events (AEs) observed in this study were chills, pyrexia, injection-site pain, nausea, flu-like symptoms and fatigue. The most common serious AEs included disease progression, cellulitis and pyrexia. No treatment-related deaths were observed.

"While there have been some important new treatment options in recent years, the incidence of melanoma has risen dramatically, and we need additional approaches for treating advanced disease," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The OPTiM trial data provide strong evidence supporting the local and distant effects of talimogene laherparepvec and its potential to stimulate a systemic anti-tumor immune response."

The OPTiM data serve as the basis of a Biologics License Application which has been accepted for review by the U.S. Food and Drug Administration (FDA), and a Marketing Authorization Application in the European Union for talimogene laherparepvec for the treatment of adults with regionally or distantly metastatic melanoma. The FDA has set a review goal date under the Prescription Drug User Fee Act of Oct. 27, 2015.

Trial Design

The OPTiM study was a global, randomized, open-label, Phase 3 trial designed to evaluate the safety and efficacy of talimogene laherparepvec compared to a control therapy with GM-CSF in over 400 patients with unresected stage IIIB, IIIC or IV melanoma.

Patients were randomized 2:1 to receive either talimogene laherparepvec intralesionally every two weeks or GM-CSF subcutaneously for the first 14 days of each 28 day cycle. Treatment could last for up to 18 months. Where appropriate, stable or responding patients could receive additional treatment on an extension protocol.

About Talimogene Laherparepvec

Talimogene laherparepvec is an investigational oncolytic immunotherapy designed to selectively replicate in tumors (but not normal tissue) and to initiate an immune response to target cancer cells that have metastasized. Talimogene laherparepvec was designed to work in two important and complementary ways. First, it is injected directly into tumors where it replicates inside the tumor's cells causing the cell to rupture and die in a process called lysis. Then, the rupture of the cancer cells can release tumor-derived antigens, along with GM-CSF, that can stimulate a system-wide immune response where white blood cells are able to seek out and target cancer that has spread throughout the body.

Amgen has initiated a comprehensive clinical development program for talimogene laherparepvec in metastatic melanoma, which includes combination studies with checkpoint inhibitors in patients with late-stage disease and monotherapy prior to surgery (neoadjuvant) in patients with resectable disease. Additionally, based on its clinical profile, talimogene laherparepvec has the potential to be studied in a variety of solid tumor types.

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 five percent of skin cancer cases, it causes the most skin cancer deaths.[3] The number of new cases of melanoma in the U.S. has been increasing for the last 30 years.[3]

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.[4]

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.

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 26, 2015, 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 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. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plan. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our 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.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/pivotal-study-results-published-in-journal-of-clinical-oncology-showed-talimogene-laherparepvec-improved-durable-response-rates-in-patients-with-metastatic-melanoma-300088873.html

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