Amgen Presents Positive Results From Talimogene Laherparepvec Phase 3 Study In Patients With Metastatic Melanoma

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THOUSAND OAKS, Calif., June 1, 2013 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced detailed results from a pivotal Phase 3 trial evaluating talimogene laherparepvec in patients with unresected stage IIIB, IIIC or IV melanoma compared to granulocyte-macrophage colony-stimulating factor (GM-CSF). The results will be presented as an oral presentation at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract No. LBA9008).

The study met its primary endpoint of durable response rate (DRR), defined as the rate of complete or partial response lasting continuously for at least six months. A statistically significant difference was observed in DRR with 16 percent in the talimogene laherparepvec arm versus two percent in the GM-CSF arm (95 percent CI, 12-21 percent, versus 95 percent CI, 0-5 percent, $p<0.0001$). The overall response rate was 26 percent with talimogene laherparepvec as compared to six percent for GM-CSF. A trend toward overall survival (HR = 0.79, 95 percent CI, 0.61-1.02) was also observed at a predefined interim analysis.

"These are the first data from a controlled trial of oncolytic immunotherapy to demonstrate activity in melanoma," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are pleased with the results of this pivotal Phase 3 trial for talimogene laherparepvec and we look forward to the mature overall survival data later this year."

In regionally and distantly metastatic melanoma (stages III and IV), cancer has spread to skin, lymph nodes, or to other organs distant from the site of origin. The DRR was highest among patients with stage III and stage IVM1a disease. The observed DRR for talimogene laherparepvec were: 33 percent in stage IIIB/IIIC, 16 percent in stage IVM1a, and three and eight percent respectively for stages IVM1b and IVM1c. The DRR with GM-CSF was not higher than four percent in any of the stage subsets.

"Over the last 30 years, the incidence of metastatic melanoma has increased by over 200 percent, so there is a need for new treatment options," said study author Robert Andtbacka, M.D., assistant professor, University of Utah Huntsman Cancer Institute. "The results of this study are encouraging in a disease as devastating as metastatic melanoma."

The most frequently observed adverse events were fatigue, chills and pyrexia. The most common serious adverse events include disease progression, cellulitis and pyrexia. Serious adverse events occurred in 26 percent of talimogene laherparepvec patients and 13 percent of GM-CSF patients.

Talimogene laherparepvec is an investigational oncolytic immunotherapy designed to work in two important and complementary ways – causing local lytic destruction of tumors while also stimulating a systemic anti-tumor immune response.

Full results will be presented today at the 2013 ASCO Annual Meeting at the Melanoma/Skin Cancers session on Saturday, June 1, 3:45 p.m. CDT, S406 (Abstract No. LBA9008).

Trial Design

This trial was a global, randomized, open-label, Phase 3 trial 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 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 United States, while melanoma accounts for less than five 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 lesion site.[3]

About Talimogene Laherparepvec

Talimogene laherparepvec is an investigational oncolytic immunotherapy designed to selectively replicate in tumor tissue. Talimogene laherparepvec is injected directly into tumor tissue and then replicates until the membrane of the cancer cells rupture, thereby destroying the cells, in a process known as cell lysis. The virus that was contained in these cells is then released locally in the tumor tissue along with GM-CSF, a white blood cell growth factor that the virus is engineered to express. This is intended to lead to the activation of a systemic immune response to kill tumor cells throughout the body.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping people around the world in the fight against serious illnesses. With a deep

and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. 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 management's current expectations and beliefs 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, including Amgen'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'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 1, 2013, 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 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 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 routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our 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.

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. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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