Amgen Presents New Data From Phase 3 Study Of Talimogene Laherparepvec In Patients With Metastatic Melanoma

September 30, 2013

THOUSAND OAKS, Calif., Sept. 30, 2013 /PRNewswire/ -- AMGEN (NASDAQ:AMGN) today announced additional 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). Results of the study's key secondary endpoints will be presented during a poster session at the 17th ECCO - 38th ESMO - 32nd ESTRO European Cancer Congress in Amsterdam (Abstract No. 3733 / P479).

New data presented include investigator assessments of response: the durable response rate (DRR) was 19 percent with talimogene laherparepvec as compared with one percent for the GM-CSF arm, and the objective response rate was 31 percent versus six percent in the GM-CSF arm. Overall there was a high degree of correlation between the independent and investigator assessments. Key secondary endpoints include time to response and duration of response by independent assessment. The median time to response was 4.1 months (range 1.2 months - 16.7 months). The duration of response was longer in the talimogene laherparepvec arm, with an estimated 68 percent of talimogene laherparepvec responders achieving responses lasting at least nine months compared to 47 percent among the GM-CSF responders.

"These results further support the primary analysis reported at ASCO which demonstrated a statistically significant durable response rate," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to the mature overall survival data expected next year."

"This is the first successful Phase 3 study of a novel oncolytic immunotherapy," said Howard Kaufman, M.D., professor and director of the section of surgical oncology in the Department of General Surgery, Rush University Medical Center in Chicago. "The fact that this study met the primary endpoint shows the value of continuing to explore the potential of talimogene laherparepvec in regional and distant 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.

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 pigment to the skin.[1] Melanoma is the most aggressive and serious form of skin cancer in which the best treatment approach involves early detection.[2] Because it is not always possible to detect cancer in its earlier stage, it can sometimes spread, or metastasize, to other parts of the body.[3] The prevalence of metastatic melanoma patients facing recurrence from an earlier stage of disease is predicted to increase by 43 percent by 2015.[4] Metastatic melanoma remains a devastating and difficult-to-treat disease with a high unmet need.

Currently, 132,000 melanoma cases occur globally each year.[5] In the U.S., while melanoma accounts for less than five percent of skin cancer cases, it causes the most skin cancer deaths.[5] The number of new cases of melanoma in the U.S. has been increasing for the last 30 years.[5]

About Talimogene Laherparepvec
Talimogene laherparepvec is an investigational oncolytic immunotherapy engineered to selectively replicate in tumor tissue. Talimogene laherparepvec is injected directly into tumor tissue and is designed to replicate until the membrane of the cancer cells rupture and release a possible array of tumor specific antigens and GM-CSF, a white blood cell growth factor that the virus is engineered to express. This is hypothesized to lead to the activation of a specific systemic immune response that targets tumor cells throughout the body.

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 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 Sept. 30, 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.

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(Logo: http://photos.prnewswire.com/prnh/20081015/AMGENLOGO)

[1]National Cancer Institute, National Institute of Health, Dept. of Health and Human Services; *What You Need to Know About Melanoma and Other Skin Cancers*; June 2010.
[2]American Cancer Society. *Surgery for Metastatic Skin Cancer*. http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-treating-surgery. Accessed August 28, 2013.
[3]American Cancer Society. *What is Metastatic Skin Cancer*. http://www.cancer.org/cancer/skincancer-melanoma/overviewguide/melanoma-skin-cancer-overview-what-is-melanoma. Accessed August 28, 2013.
[4]Lin AY, et al. Melanoma Res. 2012; 22:454-459
[5]Ultraviolet radiation and the INTERSUN Programme. World Health Organization. http://www.who.int/uv/faq/skincancer/en/index1.html. Accessed May 13, 2013.

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