Amgen And Merck Announce Collaboration To Evaluate Investigational Combination Treatment For Advanced Melanoma

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THOUSAND OAKS, Calif., Feb. 5, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Merck, known as MSD outside the United States and Canada, announced today that they have entered into an agreement through a subsidiary to evaluate the safety and efficacy of talimogene laherparepvec, an investigational oncolytic immunotherapy, combined with MK-3475, an investigational anti-PD-1 immunotherapy, in a Phase 1b/2 study of patients with mid- to late-stage melanoma.

"Talimogene laherparepvec has shown encouraging Phase 3 clinical results as a monotherapy in patients with metastatic melanoma," said David D. Chang, M.D., Ph.D., vice president of Global Development at Amgen. "We look forward to working with Merck on this collaboration to evaluate the potential of these two novel immunotherapies to improve clinical outcomes for patients."

"We are pleased to be collaborating with Amgen to study MK-3475 as part of this novel combination regimen," said Dr. Eric Rubin, vice president, clinical development for oncology, Merck Research Laboratories. "Early evaluation of immunotherapeutic combinations is important in accelerating the development of new options for patients with cancer."

The multicenter, open-label clinical trial will be conducted in two parts and is planned to begin in the fall of 2014. Phase 1b is designed to determine the safety and tolerability of talimogene laherparepvec in combination with MK-3475 in patients with previously untreated, unresected, stage IIIB to IVM1a melanoma. The Phase 2 portion will evaluate efficacy, as assessed by the confirmed objective response rate (ORR), with talimogene laherparepvec in combination with MK-3475 versus MK-3475 alone in patients with previously untreated, unresected, stage IIIB to IVM1c melanoma. The study will also evaluate the efficacy of treatment with talimogene laherparepvec in combination with MK-3475 following disease progression on MK-3475 alone.

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 MK-3475
Many tumors are able to evade the immune system through a mechanism that exploits the PD-1 inhibitory checkpoint protein. MK-3475 is an investigational, highly selective anti-PD-1 immunotherapy designed to restore the natural ability of the immune system to recognize and target cancer cells by selectively achieving dual ligand blockade (PD-L1 and PD-L2) of the PD-1 protein. By blocking PD-1, MK-3475 enables activation of the immune system's T-cells that target cancer by essentially releasing a brake on the immune system. For information on Merck's clinical trials please visit http://www.merck.com/clinical-trials/.

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 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 Feb. 5, 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 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. 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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(Logo: http://photos.prnewswire.com/prnh/20081015/AMGENLOGO)

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[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.

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