Amgen To Discuss Details Of The Biologics License Application For Talimogene Laherparepvec For Patients With Metastatic Melanoma

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Joint FDA Advisory Committee to Review Phase 3 Data for a Potential First-in-Class Oncolytic Immunotherapy

THOUSAND OAKS, Calif., April 29, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the Company will discuss the data supporting the Biologics License Application (BLA) for talimogene laherparepvec monotherapy for the treatment of patients with injectable regionally or distantly metastatic melanoma at today's joint meeting of the U.S. Food and Drug Administration's (FDA) Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) and Oncologic Drugs Advisory Committee (ODAC).

At the meeting, Amgen will present the results of the pivotal Phase 3 OPTiM study, which showed that talimogene laherparepvec monotherapy is the first oncolytic immunotherapy to demonstrate therapeutic benefit in a Phase 3 pivotal trial for patients with metastatic melanoma.

"The incidence of melanoma, the most serious form of skin cancer, has continued to rise over the last 30 years, even as many other cancers are in decline," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Despite recent advances, there is still an unmet need in this disease. For this reason, today's discussion about talimogene laherparepvec for the treatment of patients with metastatic melanoma is important. If approved, this novel agent could provide physicians and patients with an additional treatment option for this disease."

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 granulocyte-macrophage colony-stimulating factor (GM-CSF), which 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 in place 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.

According to the American Cancer Society, with an estimated 74,000 new melanoma diagnoses and nearly 10,000 deaths this year[1], melanoma remains a significant public health concern in the U.S. Additionally, metastatic melanoma continues to be one of the most difficult to treat cancers because it is highly aggressive and complex. Despite recent treatment advances, the five-year survival rate for melanoma is only 20 percent[2], so additional safe and effective treatment options are needed.

OPTiM Study Design and Results
Study 005/05, referred to as OPTiM, was a Phase 3, multicenter, open-label, randomized clinical trial comparing talimogene laherparepvec to GM-CSF in patients with advanced melanoma (stage IIIB, IIIC, or IV) that was not surgically resectable. The primary endpoint of the study was durable response rate (DRR).

In the 436-patient study, talimogene laherparepvec significantly improved DRR with 16.3 percent of talimogene laherparepvec patients achieving a complete response (CR) or partial response (PR) within the first 12 months of treatment and maintaining it continuously for at least six months compared to 2.1 percent of patients treated with GM-CSF (p <0.001).

The OPTiM study also provided additional secondary and exploratory data that demonstrated the effects of talimogene laherparepvec in patients with Stage III/IV metastatic melanoma, including:

- Improved overall (CR + PR) response rate compared with GM-CSF, 26.4 percent vs. 5.7 percent, respectively. In particular, the CR rate was higher in the talimogene laherparepvec arm than in the GM-CSF arm (10.8 percent vs. 0.7 percent, respectively).
- A strong trend in overall survival (OS). The median OS was 4.4 months longer in the talimogene laherparepvec arm than in the GM-CSF arm (hazard ratio: 0.79; p=0.051).
- Evidence of a systemic effect. Eight of 71 patients (11.3 percent) with visceral lesions that could not be injected (predominately in the lung and liver) had an overall decrease in those lesions of more than 50 percent.

The most commonly reported treatment-related adverse events were fatigue, chills, pyrexia, nausea, influenza-like illness, and injection-site pain. Most adverse reactions reported were mild or moderate in severity and generally resolved within 72 hours. The most common serious adverse reaction was cellulitis.

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, we 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 April 29, 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 our ability to pay a dividend or repurchase 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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2.American Cancer Society. Melanoma Skin Cancer. http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-survival-rates. Accessed April 13, 2015.

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