Amgen Presents New Data On Talimogene Laherparepvec As Single Agent And Combination Therapy In Metastatic Melanoma At ASCO

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Phase 1 Study Evaluating Talimogene Laherparepvec Plus Ipilimumab Showed Tolerability at Doses Administered
Tumors Shrank in Size or Were No Longer Detectable in 56 Percent of Patients
Positive Overall Survival Trend Observed in Phase 3 Study

THOUSAND OAKS, Calif., June 2, 2014 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced new data from two key clinical trials that support the potential of talimogene laherparepvec, a novel, investigational oncolytic immunotherapy, as both a single agent and as part of a combination regimen in patients with metastatic melanoma. The findings were presented at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

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Data from the 19 patients in the Phase 1b combination study, presented for the first time at ASCO, showed no dose-limiting toxicities with talimogene laherparepvec in combination with ipilimumab (Abstract #9029). Additionally, tumors either shrank in size or were no longer detectable in 56 percent of patients when talimogene laherparepvec was given prior to and in combination with ipilimumab. The most common adverse events observed were chills, fevers, rash and fatigue.

"We are entering an era where new melanoma therapies are advancing clinical care for patients in ways not previously seen," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Talimogene laherparepvec has demonstrated the ability to produce durable and complete responses in patients with metastatic melanoma which provides a strong basis for a filing later this year and potential approval of talimogene laherparepvec as a novel treatment for this devastating disease."

As previously reported, the pivotal Phase 3 trial met its primary endpoint showing a statistically significant improvement in durable response rate (16 percent in the talimogene laherparepvec arm versus two percent in the granulocyte-macrophage colony-stimulating factor [GM-CSF]). Among the 26 percent of patients who achieved an overall response (n=78) in the talimogene laherparepvec arm, 40 percent achieved a complete response (no evidence of disease). Data presented today showed that among the talimogene laherparepvec responders, there was a 65 percent probability of responses lasting for at least 12 months.

Detailed results of the overall survival analysis, a key secondary endpoint of the pivotal Phase 3 trial evaluating talimogene laherparepvec as a single agent, were also presented (Abstract #9008a). The results demonstrated a 4.4 month improvement in overall survival (HR=0.79; *p*=0.051) which closely approached statistical significance in the total patient population tested that included patients with and without visceral tumors (tumors involving solid organs such as the lungs and liver).The most frequent adverse events observed in this trial were fatigue, chills and pyrexia. The most common serious adverse events include disease progression, cellulitis and pyrexia.

"Novel investigational therapies are creating exciting momentum in melanoma research and our challenge is to better understand how to most appropriately develop these therapies," said Igor Puzanov, M.D., associate professor of Medicine at Vanderbilt-Ingram Cancer Center and lead author on the Phase 1b combination study. "These latest findings support the potential of talimogene laherparepvec as a single agent and provide a strong rationale for further investigation as a combination therapy in a broad range of appropriate patients."

Phase 1b/2 Trial Design
The Phase 1b/2, multicenter, open-label trial enrolled patients with unresected Stage IIIB-IV melanoma (58 percent of patients were Stage IV), no prior systemic treatment, measurable disease, and more than one injectable cutaneous, subcutaneous or nodal lesion (n=19). Talimogene laherparepvec was administered by intratumoral injection on day 1 of week 1, day 1 of week 4, and then every two weeks thereafter. Ipilimumab was administered intravenously on day 1 of week 6, week 9, week 12, and week 15 for a total of four infusions. Patients were treated with talimogene laherparepvec until complete response, all injectable tumors disappeared, disease progression per a modified immune-related response criteria (irRC), or intolerance of study treatment.

Phase 3 Trial Design
The Phase 3 pivotal trial was a global, randomized, open-label trial to evaluate the safety and efficacy of talimogene laherparepvec compared to a control therapy (GM-CSF) in over 400 patients with unresected stage IIIB, IIIC or IV melanoma. The primary endpoint was durable response rate defined as the rate of complete response or partial response lasting continuously for six or more months, as compared to control therapy. Overall survival was a secondary endpoint.

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.

Amgen Post-ASCO Summary Webcast
Amgen will hold a post-ASCO summary webcast on Tuesday, June 3, 2014, at 1 p.m. PT. Sean E. Harper, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team will participate to discuss data presented at ASCO and Amgen's broader oncology portfolio of products.

Live audio of the conference call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and

medical conferences, can be found on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

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. 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.

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.[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 tumor 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 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 June 2, 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 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 Amgen and its partners routinely obtain patents for 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.

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.

CONTACT: Amgen
Kristen Davis, 805-447-3008 (media)
Arvind Sood, 805-447-1060 (investors)

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