Amgen to Present IMLYGIC™ (Talimogene Laherparepvec) Data at the 2015 International Congress of the Society for Melanoma Research

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Highlights Include Analyses From Pivotal Study and New Data From Phase 1b Combination Trial in Metastatic Melanoma

THOUSAND OAKS, Calif., Nov. 16, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the Company will present eight IMLYGIC™ (talimogene laherparepvec) abstracts, including data from the Phase 3 trial and new data from its Phase 1b combination trial with Merck's anti-PD-1 therapy, at the 12th International Congress of the Society for Melanoma Research (SMR), to be held on Nov. 18-21 in San Francisco.

"The analyses from our Phase 3 monotherapy trial confirm the clinical significance of durable responses and the benefit IMLYGIC may bring to patients living with metastatic melanoma," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "As we advance understanding in the emerging science of oncolytic viral therapy, we are also excited to share early data on the use of IMLYGIC in combination with another immunotherapy."

The Phase 1b data on IMLYGIC in combination with an investigational use of Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with unresectable metastatic melanoma (NCT02263508) has been accepted as a late-breaking abstract. The oral presentation is Saturday, Nov. 21, in Plenary Session 11 (Late Breaking Clinical Updates) between 1:30 to 3:40 p.m. PT in the San Francisco Marriott Marquis Salon 9-15:

- **Primary analysis of MASTERKEY-265 phase 1b study of talimogene laherparepvec (T-VEC) and pembrolizumab (pembro) for unresectable stage IIIB-IV melanoma** (G. Long)

Additionally, the Company will present analyses from OPTiM, the Phase 3 trial that served as the basis of the U.S. Food and Drug Administration's (FDA) approval of IMLYGIC in October 2015. The following will be presented on Thursday, Nov. 19, from 6 to 8 p.m. PT at the Poster Reception in the San Francisco Marriott Marquis Salon 1-8:

- **Safety profile of talimogene laherparepvec (T-VEC) in OPTiM, a phase 3 trial for melanoma** (F. Collichio)
- **Long-term follow up from the phase 2 study of talimogene laherparepvec (T-VEC) for metastatic melanoma** (J. Nemunaitis)
- **Durable-response (DR)-associated benefits in patients (pts) with unresected stage IIIB-IV melanoma treated with talimogene laherparepvec (T-VEC) or GM-CSF in OPTiM** (H. Kaufman)
- **Durable complete responses (CR) in patients (pts) with stage IIIB-IV melanoma treated with talimogene laherparepvec (T-VEC) in OPTiM** (R. Andtbacka)
- **Reduced risk of developing visceral/bone metastasis (VM) in patients (pts) with stage IIIB/C/IVM1a melanoma treated with talimogene laherparepvec (T-VEC) vs GM-CSF** (R. Andtbacka)
- **Did patients in OPTiM have truly unresectable disease? Results of an independent review** (M. Faries)
- **Current treatment patterns in patients with metastatic melanoma: A retrospective claims database analysis in the United States (U.S.)** (Y. Chen)

Abstracts are available on the SMR website at www.melanomacongress.com/abstracts.

About IMLYGIC ™(talimogene laherparepvec)
IMLYGIC is a genetically modified herpes simplex type 1 virus that is injected directly into tumors. IMLYGIC replicates inside tumor cells and produces GM-CSF, an immunostimulatory protein. IMLYGIC then causes the cell to rupture and die in a process called lysis. The rupture of the cancer cells causes the release of tumor-derived antigens, which together with virally derived GM-CSF may help to promote an anti-tumor immune response. However, the exact mechanism of action is unknown.

IMLYGIC is the first oncolytic viral therapy approved by the FDA based on therapeutic benefit demonstrated in a pivotal study. IMLYGIC is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. IMLYGIC has not been shown to improve overall survival or have an effect on visceral metastases.

Important Safety Information

Contraindications

- Do not administer IMLYGIC™ to immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy, due to the risk of life-threatening disseminated herpetic infection.
- Do not administer IMLYGIC™ to pregnant patients.

Warnings and Precautions

- **Accidental exposure to IMLYGIC™** may lead to transmission of IMLYGIC™ and herpetic infection, including during preparation and administration. Health care providers, close contacts, pregnant women, and newborns should avoid direct

contact with injected lesions, dressings, or body fluids of treated patients. The affected area in exposed individuals should be cleaned thoroughly with soap and water and/or a disinfectant.

- Caregivers should wear protective gloves when assisting patients in applying or changing occlusive dressings and observe safety precautions for disposal of used dressings, gloves, and cleaning materials. Exposed individuals should clean the affected area thoroughly with soap and water and/or a disinfectant.
- To prevent possible inadvertent transfer of IMLYGIC™ to other areas of the body, patients should be advised to avoid touching or scratching injection sites or occlusive dressings.
- **Herpetic infections:** Herpetic infections (including cold sores and herpetic keratitis) have been reported in IMLYGIC™-treated patients. Disseminated herpetic infection may also occur in immunocompromised patients. Patients who develop suspicious herpes-like lesions should follow standard hygienic practices to prevent viral transmission.
- Patients or close contacts with suspected signs or symptoms of a herpetic infection should contact their health care provider to evaluate the lesions. Suspected herpetic lesions should be reported to Amgen at 1-855-IMLYGIC (1-855-465-9442). Patients or close contacts have the option of follow-up testing for further characterization of the infection.
- IMLYGIC™ is sensitive to acyclovir. Acyclovir or other antiviral agents may interfere with the effectiveness of IMLYGIC™. Consider the risks and benefits of IMLYGIC™ treatment before administering antiviral agents to manage herpetic infection.
- **Injection Site Complications:** Necrosis or ulceration of tumor tissue may occur during IMLYGIC™ treatment. Cellulitis and systemic bacterial infection have been reported in clinical studies. Careful wound care and infection precautions are recommended, particularly if tissue necrosis results in open wounds.
- Impaired healing at the injection site has been reported. IMLYGIC™ may increase the risk of impaired healing in patients with underlying risk factors (e.g., previous radiation at the injection site or lesions in poorly vascularized areas). If there is persistent infection or delayed healing of the injection site, consider the risks and benefits of continuing treatment.
- **Immune-Mediated events** including glomerulonephritis, vasculitis, pneumonitis, worsening psoriasis, and vitiligo have been reported in patients treated with IMLYGIC™. Consider the risks and benefits of IMLYGIC™ before initiating treatment ir patients who have underlying autoimmune disease or before continuing treatment in patients who develop immune-mediated events.
- **Plasmacytoma at Injection Site:** Plasmacytoma in proximity to the injection site has been reported in a patient with smoldering multiple myeloma after IMLYGIC™ administration in a clinical study. Consider the risks and benefits of IMLYGIC™ in patients with multiple myeloma or in whom plasmacytoma develops during treatment.

Adverse Reactions

- The most commonly reported adverse drug reactions (≥ 25%) in IMLYGIC™-treated patients were fatigue, chills, pyrexia, nausea, influenza-like illness, and injection site pain. Pyrexia, chills, and influenza-like illness can occur at any time during IMLYGIC™ treatment, but were more frequent during the first 3 months of treatment.
- The most common Grade 3 or higher adverse reaction was cellulitis.

Please see full Prescribing Information and Medication Guide for IMLYGIC™ at www.IMLYGIC.com.

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 Nov. 16, 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 ongoing 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 relating to new indications for Amgen's products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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