Amgen Presents Phase 3 Data At ASCO Showing Prolia® (Denosumab) Significantly Reduced Bone Fractures In Breast Cancer Patients Receiving Aromatase Inhibitors

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Study Shows Adjuvant Prolia Therapy Reduced Fractures by 50 Percent in Postmenopausal Women With Non-Metastatic Breast Cancer

Online Publication in The Lancet to Coincide With ASCO Presentation

THOUSAND OAKS, Calif., June 1, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced results from a randomized, double-blind, placebo-controlled, multicenter Phase 3 study evaluating the treatment effect of adjuvant Prolia® (denosumab), 60 mg once every six months, therapy in postmenopausal women with early hormone receptor positive (HR+) breast cancer receiving aromatase inhibitor therapy. The trial met its primary endpoint of time from randomization to first clinical fracture (HR=0.5, 95 percent CI 0.39-0.65, p<0.0001). The observed 50 percent reduction in fractures between the Prolia and placebo arms, 92 versus 176, respectively, was similar in patients with normal bone health at baseline (n=1,872, HR=0.44, p<0.0001) and in patients who started the trial with early signs of bone loss (n=1,548, HR=0.57, p=0.0021). The data will be presented at the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago today at 9:12 a.m. CT (abstract no. 504). In addition to the presentation, the paper was published online by *The Lancet*.

This is the first Prolia trial to enroll patients independent of baseline bone mineral density (BMD) and with the majority in the normal BMD range. The study, which enrolled a total of 3,425 patients, was conducted by the Austrian Breast and Colorectal Cancer Study Group (ABCSG).

"Fracture is a common side effect of aromatase inhibitors, which are an important first-line therapy for postmenopausal women with non-metastatic breast cancer," said principal investigator Michael Gnant, professor of surgery at Medical University of Vienna. "These encouraging data demonstrate the potential benefit of initiating Prolia simultaneously with aromatase inhibitor therapy, regardless of the patient's baseline BMD, to decrease the risk of fracture."

Evaluation of key secondary endpoints showed that Prolia reduced the incidence of new vertebral and new or worsening of pre-existing vertebral fractures at 36 months (p<0.01). Statistically significant increases in BMD of the lumbar spine, total hip and femoral neck were observed in the Prolia-treated group at 36 months. The other secondary endpoints of disease-free survival, bone metastasis-free survival and overall survival have not read out yet.

The safety profile of Prolia therapy was similar to placebo, and no major safety events were reported. The most frequently reported adverse events in this study included arthralgia, hot flush, back pain, osteoarthritis and bone pain.

"Our continued research into Prolia reinforces Amgen's ongoing commitment to exploring the potential role this medicine can have in breast cancer treatment," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Breast cancer patients can be affected by bone loss and its repercussions, and this study provides new evidence of the clinical profile for Prolia in this important setting."

About Prolia® (denosumab)

Prolia is the first approved therapy that specifically targets RANK Ligand, an essential regulator of bone-removing cells (osteoclasts).

Prolia is approved in the U.S. for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. Prolia is also approved for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Prolia is approved in the EU plus Switzerland, Norway, Iceland and Liechtenstein for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. Prolia is also approved in the EU for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

Prolia is also indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer.

Prolia is administered as a single subcutaneous injection of 60 mg once every six months. Please see the Important Safety Information below.

Important Safety Information (U.S.)

Prolia is contraindicated in patients with hypocalcemia. Preexisting hypocalcemia must be corrected prior to initiating Prolia. Prolia is contraindicated in women who are pregnant and may cause fetal harm. Prolia is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling and urticaria. Prolia contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia should not receive XGEVA®.

Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia. Hypocalcemia may worsen in patients taking Prolia, especially in patients with severe renal impairment. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia injection. Adequately supplement all patients with calcium and vitamin D.

Osteonecrosis of the jaw (ONJ), which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing and has been reported in patients receiving Prolia. A routine oral exam should be performed by the prescriber prior to initiation of Prolia. A dental examination with appropriate preventive dentistry is recommended prior to treatment with Prolia in patients with risk factors for ONJ such as

invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g., chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders. Good oral hygiene practices should be maintained during treatment. For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia therapy should be considered based on individual benefit-risk assessment.

Atypical low-energy or low trauma fractures of the shaft have been reported in patients receiving Prolia. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with antiresorptive agents. During Prolia treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of Prolia therapy should be considered, pending a risk/benefit assessment, on an individual basis.

In a clinical trial (N= 7800) in women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported more frequently in the Prolia group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear were more frequent in patients treated with Prolia. Endocarditis was also reported more frequently in Prolia-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis. Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia, prescribers should assess the need for continued Prolia therapy.

In the same clinical trial in women with postmenopausal osteoporosis, epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate with Prolia compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia if severe symptoms develop.

Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia. Consider discontinuing use if severe symptoms develop. Suppression of Bone Turnover In clinical trials in women with postmenopausal osteoporosis, Prolia resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for these consequences, including ONJ, atypical fractures, and delayed fracture healing.

It is not known whether Prolia is excreted into human milk. Measurable concentrations of denosumab were present in the maternal milk of cynomolgus monkeys up to 1 month after the last dose of denosumab (≤ 0.5% milk:serum ratio). Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Prolia, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

The most common adverse reactions (>5% and more common than placebo) in women with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. The most common adverse reactions (> 5% and more common than placebo) in men with osteoporosis are back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with Prolia. In women with postmenopausal osteoporosis, the overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia groups. In men with osteoporosis, new malignancies were reported in no patients in the placebo group and 4 (3.3%) patients in the Prolia group. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity. The most common (per patient incidence ≥ 10%) adverse reactions reported with Prolia in patients with bone loss receiving ADT for prostate cancer or adjuvant AI therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials. Additionally, in Proliatreated men with nonmetastatic prostate cancer receiving ADT, a greater incidence of cataracts was observed.

For more information, please see the Prolia Important Safety Information, Prescribing Information, and Medication Guide.

The Prolia Postmarketing Active Safety Surveillance Program is available to collect information from prescribers on specific adverse events. Please see https://www.proliasafety.com/ or call 18007726436 for more information.

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 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, we are providing this information as of June 1, 2015, and expressly disclaim 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 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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