FDA Approves New Indications for Prolia® (Denosumab) for the Treatment of Bone Loss in Patients With Prostate or Breast Cancer Undergoing Hormone Ablation Therapy

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Prolia is the First-and-Only Medicine Approved for Cancer Treatment-Induced Bone Loss

THOUSAND OAKS, Calif., Sept. 19, 2011 /PRNewswire via COMTEX/ --

Amgen (NASDAQ: AMGN) today announced that the U.S. Food and Drug Administration (FDA) approved two new indications for Prolia® (denosumab) as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. In patients with prostate cancer, Prolia also reduced the incidence of vertebral fractures. Prolia is the first-and-only therapy approved by the FDA for cancer treatment-induced bone loss in patients undergoing hormone ablation therapy.

Aromatase inhibitors are often used in patients with breast cancer to prevent recurrence of disease, and androgen deprivation therapy is often used in patients with prostate cancer to prevent or control recurrent disease. These treatments reduce hormone levels, leading to bone loss and an increased risk of fracture.

"Bone loss and fractures are recognized adverse effects of hormone ablation therapies but we have not had an approved treatment option to prevent these problems for our patients," said Matthew Smith, M.D., Ph.D., director of the Genitourinary Malignancies Program at Massachusetts General Hospital Cancer Center, Boston. "Prolia now gives us the ability to reduce the risk of bone loss and fractures, allowing patients to continue their treatment and their fight against cancer."

The expanded indications for Prolia are based on two Phase 3 clinical trials: a three year, randomized, double-blind, placebo-controlled, multinational study involving 1,468 men with non-metastatic prostate cancer undergoing androgen deprivation therapy, and a two year, double-blind, placebo-controlled, multinational study involving 252 postmenopausal women with breast cancer receiving aromatase inhibitor therapy.(i)

In men, bone mineral density (BMD) was significantly higher at the lumbar spine in patients treated with Prolia for two years compared to placebo (-1.0 percent placebo, +5.6 percent Prolia; treatment difference 6.7 percent [95 percent CI: 6.2, 7.1]; P<0.0001). Additionally, after three years of treatment with Prolia, differences in BMD were 7.9 percent at the lumbar spine, 5.7 percent at the (total) hip and 4.9 percent at the femoral neck and the incidence of new vertebral fractures was 3.9 percent in the placebo-treated men compared to 1.5 percent for the Prolia-treated men, representing a relative risk reduction of 62 percent (P=0.0125).

In women, BMD was higher at 12 months at the lumbar spine in patients treated with Prolia as compared to placebo (-0.7 percent placebo, +4.8 percent Prolia; treatment difference 5.5 percent [95 percent CI: 4.8, 6.3]; P<0.0001). Additionally, after two years of treatment with Prolia differences in BMD were 7.6 percent at the lumbar spine, 4.7 percent at the (total) hip and 3.6 percent at the femoral neck.

The most common (per patient incidence ≥ 10 percent) adverse reactions reported with Prolia in patients with bone loss receiving androgen deprivation therapy for prostate cancer or adjuvant aromatase inhibitor therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials. Additionally, in Prolia-treated men with non-metastatic prostate cancer receiving androgen deprivation therapy, a greater incidence of cataract adverse events was reported. Hypocalcemia was reported in Prolia-treated patients.

About Prolia

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

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 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. In these patients with prostate cancer, Prolia reduced the incidence of vertebral fractures.

Prolia is approved in the European Union (EU) for the treatment of osteoporosis in postmenopausal women at increased risk of fractures, and for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

Prolia is approved in the U.S., Canada, Australia, and in all 27 EU member states as well as in Norway, Iceland and Liechtenstein. Applications in the rest of the world are pending.

Prolia is administered as a single subcutaneous injection of 60 mg once every six months. For further information on Prolia, including prescribing information and medication guide, please visit: www.prolia.com.

Important U.S. Safety Information

Prolia is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia. Hypocalcemia may worsen, especially in patients with severe renal impairment. All patients should be adequately supplemented with calcium and vitamin D. Patients receiving Prolia should not receive XGEVA®, as both Prolia and XGEVA contain the same active ingredient, denosumab.

In the Phase 3 pivotal study of women with postmenopausal osteoporosis (n=7808), serious infections leading to hospitalizations were reported more frequently in the Prolia-treated patient group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia. Patients should be advised to seek prompt medical attention if they develop signs or symptoms of severe infection,

including cellulitis. Endocarditis was reported more frequently in the Prolia-treated patient group. Epidermal and dermal adverse events such as dermatitis, rashes and eczema have been reported. Discontinuation of Prolia should be considered if severe symptoms develop.

In clinical trials in women with postmenopausal osteoporosis, Prolia resulted in significant suppression of bone remodeling. The significance of these findings is unknown. The long-term consequences of the degree of suppression of bone remodeling observed with Prolia may contribute to adverse outcomes such as osteonecrosis of the jaw (ONJ), atypical fractures and delayed fracture healing. ONJ has been reported in patients with Prolia. Patients should be monitored for these adverse outcomes.

The most common adverse reactions (> 5 percent and more common than placebo) in patients with postmenopausal osteoporosis were back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia and cystitis. Pancreatitis has also been reported. The most common (per patient incidence $\geq$ 10 percent) adverse reactions reported with Prolia in patients with bone loss receiving androgen deprivation therapy for prostate cancer or adjuvant aromatase inhibitor therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com. 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 most recent 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 Sept. 19, 2011, 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 products liability claims. 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 payors, 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.

The scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (FDA) 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. Only the FDA can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

(i) Prolia® (denosumab) prescribing information, Amgen.

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