Amgen to Discuss Application for New Use of XGEVA® (denosumab) at FDA Oncologic Drugs Advisory Committee Meeting

February 8, 2012

THOUSAND OAKS, Calif., Feb. 8, 2012 /PRNewswire/ -- Amgen (NASDAQ: AMGN) will discuss the data from the supplemental Biologics License Application (sBLA) for XGEVA® (denosumab) to treat men with castration-resistant prostate cancer (CRPC) at high risk of developing bone metastases (spread of cancer to the bone) at today's meeting of the U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC).

Amgen will discuss results of the pivotal Phase 3 '147 trial, which forms the basis for the proposed new indication. If approved in this expanded indication, XGEVA would become the first therapy licensed to prevent or delay the spread of cancer to bone in men with CRPC. XGEVA is currently approved to prevent skeletal-related events (SREs) in men with advanced prostate cancer that has already spread to the bone.

"The development of bone metastasis is an irreversible, life-changing event for men living with castration-resistant prostate cancer and is associated with significant and progressive morbidity," said Sean Harper, M.D., senior vice president of Global Development and chief medical officer at Amgen. "XGEVA is the first agent to prolong bone metastasis-free survival and addresses this important unmet medical need."

Bone metastases weaken the skeleton and can result in incapacitating complications known as SREs, which include fracture, spinal cord compression, radiation and surgery to bone. An estimated 54,000 patients in the U.S. have CRPC with a high risk of developing bone metastases.

'147 Study Design & Results

Study '147 was a randomized, placebo-controlled, multicenter Phase 3 study comparing the treatment effect of XGEVA to placebo in prolonging bone metastasis-free survival, a measure of the time that patients live without progressing to bone metastases. The study enrolled 1,432 men with CRPC who had no bone metastases at baseline, but were at increased risk based on prostate specific antigen (PSA) criteria. The '147 study enrolled patients with a PSA greater than or equal to 8 ng/mL or PSA doubling time of 10 or less months.

The primary analysis of the overall '147 study population showed that XGEVA significantly reduced the risk for bone metastases or death by 15 percent and increased bone metastasis-free survival, or the time a patient went without developing bone metastasis, by a median of 4.2 months (29.5 versus 25.2 months, respectively; p=0.028). In exploratory analyses of patients with PSA doubling time of 10 months or less (80 percent of the study population), XGEVA prolonged median bone metastasis-free survival time by 6.0 months compared with placebo with a 16 percent reduction in risk. In patients with PSA doubling time of 6 months or less, XGEVA prolonged median bone metastasis-free survival time by 7.2 months compared with placebo with a 23 percent reduction in risk.

Further supporting the clinical relevance of its effects, XGEVA reduced the risk of symptomatic bone metastases by 33 percent and the risk of multiple bone metastases by 24 percent.

Overall survival was similar (HR 1.01; 95 percent CI: 0.85, 1.20; p=0.91) between the XGEVA and placebo groups. The study was not designed to show an overall survival benefit. Patients were taken off treatment once they developed a bone metastasis so they could receive the standard approved treatment for metastatic cancer at the time the study was conducted.

No new safety risks were identified in the study. Adverse events and serious adverse events were relatively similar between the XGEVA and placebo arms. The known risks of hypocalcemia (1.7 percent) and osteonecrosis of the jaw (ONJ) (4.6 percent) were reported with increased frequencies in the XGEVA-treated patients. The yearly rate of ONJ in the XGEVA arm was similar to prior XGEVA trial results. Back pain was the most common adverse event reported in the XGEVA arm of the trial.

About XGEVA

XGEVA is the first-and-only RANK Ligand inhibitor approved by the FDA for the prevention of SREs in patients with bone metastases from solid tumors. XGEVA was initially approved following a six month priority review by the FDA. XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma. XGEVA is the first novel bone metastases treatment for advanced cancer patients in nearly a decade. Delivered as an every four week 120 mg subcutaneous injection, XGEVA provides a unique option for urologists and oncologists to prevent SREs in patients with bone metastases from solid tumors.

XGEVA is a fully human monoclonal antibody that binds to RANK Ligand, a protein essential for the formation, function and survival of osteoclasts (the cells that break down bone). XGEVA prevents RANK Ligand from activating its receptor, RANK, on the surface of osteoclasts, thereby decreasing bone destruction.

XGEVA has been studied in over 6,000 patients with cancer. In clinical trials, XGEVA demonstrated a clinically meaningful improvement compared to the previous standard of care in preventing bone complications. XGEVA is also being investigated for the potential use to delay the onset of bone metastasis in adjuvant breast cancer.

XGEVA Important Safety Information

XGEVA can cause severe hypocalcemia. Correct pre-existing hypocalcemia prior to XGEVA treatment. Monitor calcium levels and administer calcium, magnesium and vitamin D as necessary. Advise patients to contact a healthcare professional for symptoms of hypocalcemia.

Osteonecrosis of the jaw (ONJ) can occur in patients receiving XGEVA. Patients who are suspected of having or who develop ONJ while on XGEVA should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

The most common adverse reactions in patients receiving XGEVA were fatigue/asthenia, hypophosphatemia and nausea. The most common serious

adverse reaction in patients receiving XGEVA was dyspnea. The most common adverse reactions resulting in discontinuation of XGEVA were osteonecrosis and hypocalcemia. Please visit www.amgen.com or www.xgeva.com for full U.S. prescribing information.

XGEVA Regulatory Status

XGEVA has been approved in the U.S., Canada, the European Union (EU), Switzerland, Australia, Russia, Japan and Mexico for the prevention of SREs in patients with bone metastases from solid tumors. XGEVA is not approved to prevent SREs in patients with multiple myeloma.

Amgen has also submitted marketing applications for XGEVA in South Africa, Gulf Cooperation Council countries, Morocco and Egypt. In Japan, Amgen is working with its licensing partner, Daiichi Sankyo Company, Limited. In addition, Amgen and GlaxoSmithKline (GSK) have a collaboration agreement for the commercialization of XGEVA in a number of countries where Amgen does not currently have a commercial presence. In these countries, marketing applications are filed by GSK.

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 Feb. 8, 2012 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.

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