The Lancet Publishes Results Demonstrating XGEVA® Significantly Prolonged Bone Metastasis-free Survival in Men With Prostate Cancer

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XGEVA Prevented or Delayed the Onset of Bone Metastases in Patients With Prostate Cancer

THOUSAND OAKS, Calif., Nov. 15, 2011 /PRNewswire via COMTEX/ --

Amgen (NASDAQ: AMGN) announced today the publication of results from a Phase 3 trial (the '147 study) that evaluated XGEVA® (denosumab) for use in preventing or delaying the onset of bone metastases in men with nonmetastatic castration-resistant prostate cancer (CRPC). Published in *The Lancet*, the study found XGEVA significantly prolonged bone metastasis-free survival, delayed time to bone metastasis and reduced the risk of symptomatic bone metastases. This study is the first to demonstrate that targeting the bone microenvironment prevents bone metastasis in men with prostate cancer.

"The prevention of bone metastases is a major unmet medical need for men with castration-resistant prostate cancer. Bone metastases are a significant concern for these patients who have historically had poor outcomes," Matthew Smith, M.D., Ph.D., professor of medicine and the director of Genitourinary Oncology at Massachusetts General Hospital Cancer Center. "The more than four-month increase in bone metastasis-free survival with XGEVA treatment is a clinically significant finding that has the potential to improve the management of men living with prostate cancer."

Based on the results of this study, Amgen filed a supplemental Biologics License Application (sBLA) to expand the indication for XGEVA to treat men with CRPC to reduce the risk of developing bone metastases. The U.S. Food and Drug Administration (FDA) has set April 26, 2012 as the targeted Prescription Drug User Fee Act (PDUFA) action date for the sBLA. If approved, XGEVA would be the first-and-only therapy licensed to prevent or delay the spread of cancer to the bone.

Study Results

In the '147 study, XGEVA significantly improved median bone metastasis-free survival by 4.2 months, a risk reduction of 15 percent, compared with placebo (29.5 versus 25.2 months, respectively; hazard ratio (HR) 0.85; 95 percent CI: 0.73, 0.98; p=0.028). XGEVA significantly delayed the time to first bone metastases by 3.7 months compared with placebo (HR 0.84; 95 percent CI: 0.71, 0.98; p=0.032; risk reduction of 16 percent). XGEVA also reduced the risk of bone metastases that were symptomatic by 33 percent (HR 0.67; 95 percent CI: 0.49, 0.92; p=0.01). Overall survival was similar between groups (HR 1.01; 95 percent CI: 0.85, 1.20; p=0.91). The study design required that patients discontinue XGEVA following development of bone metastasis so that they could receive standard approved treatment for prevention of skeletal-related events (SREs), therefore, the potential to measure a positive impact on survival was limited.

In the '147 trial, adverse events and serious adverse events were relatively similar between the XGEVA and placebo arms. Hypocalcemia and osteonecrosis of the jaw (ONJ) 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.

Study Design

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 - in 1,432 men with hormone-refractory (castration-resistant) prostate cancer who had no bone metastases at baseline but were at increased risk of developing them based on their prostate specific antigen (PSA) criteria. The primary endpoint of the trial was time to first occurrence of bone metastases or death from any cause with secondary endpoints including time to first occurrence of bone metastases (excluding death) and overall survival.

About XGEVA

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 is the first novel bone metastases treatment for advanced cancer patients in nearly a decade. XGEVA is delivered as an every four week 120 mg subcutaneous injection and does not require dose adjustment regardless of renal function.

XGEVA is the first-and-only RANK Ligand inhibitor approved by the FDA indicated for the prevention of SREs in patients with bone metastases from solid tumors. XGEVA was approved following a six month priority review by the FDA. XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma.

The European Commission (EC) granted a Marketing Authorization for XGEVA for the prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumors. As part of the review, the EC also granted XGEVA one additional year of marketing protection based on the indication being considered new for denosumab and the significant clinical benefit offered by the product in comparison with existing therapies. XGEVA also has similar indications to prevent SREs in Canada and Australia.

Amgen has also submitted marketing applications for XGEVA in Mexico, Russia and Switzerland. In Japan, Amgen is working with its licensing partner, Daiichi Sankyo Company, Limited and a marketing application was submitted. 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.

XGEVA has been studied in over 7,000 patients with cancer. In clinical trials, XGEVA demonstrated a clinically meaningful improvement compared to the 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.

For more information on XGEVA, please visit http://www.xgeva.com/.

XGEVA Important Safety Information

XGEVA can cause severe hypocalcemia. Correct pre-existing hypocalcemia prior to XGEVA treatment. Monitor calcium levels in patients at greater risk of developing hypocalcemia. Administer calcium and vitamin D in all patients (unless hypercalcemia is present). 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.

Adverse reactions in patients receiving XGEVA included fatigue/asthenia, hypophosphatemia, nausea, dyspnea and diarrhea.

Please visit http://www.amgen.com/ for full U.S. prescribing information.

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 http://www.amgen.com/. Follow us on www.twitter.com/amgen.

Forward Looking Statements

This statement 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 Nov. 15, 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 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 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 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. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Further, 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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