Amgen Receives Complete Response Letter From FDA for XGEVA® sBLA for Prevention of Bone Metastases

April 27, 2012

THOUSAND OAKS, Calif., April 26, 2012 /PRNewswire via COMTEX/ --Amgen (NASDAQ: AMGN) today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter for 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.

The Complete Response Letter states that FDA cannot approve the application in its present form. The FDA determined that the effect on bone metastases-free survival (BMFS) was of insufficient magnitude to outweigh the risks (including osteonecrosis of the jaw) of XGEVA in the intended population, and requested data from an adequate and well-controlled trial(s) demonstrating a favorable risk-benefit profile for XGEVA that is generalizable to the U.S. population.

"We are reviewing the complete response letter and will work with FDA to determine any next steps," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The FDA's action today does not impact the approved indication of XGEVA in the prevention of skeletal-related events in men with bone metastases from prostate cancer, which was acknowledged by the FDA and the advisory committee members who discussed the application."

About XGEVA
XGEVA is the first-and-only RANK Ligand inhibitor approved by the FDA for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors, including prostate cancer. 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 and disease-free survival in the adjuvant treatment of 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), Australia, Russia, Argentina, Switzerland, and Israel 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.

XGEVA has been approved in Mexico for the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with advanced malignancies involving bone. In Japan, Amgen is working with its licensing partner, Daiichi Sankyo Company, Limited, and denosumab is approved as RANMARK® for treatment for bone complications stemming from multiple myeloma and bone metastases from solid tumors.

Amgen has also submitted marketing applications for XGEVA in South Africa, Gulf Cooperation Council countries, Morocco and Egypt. 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 Amgen'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 statements about the planned completion of the tender offer and regulatory filings. 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 Amgen's business. Unless otherwise noted, Amgen is providing this information as of April 26, 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 Amgen's 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 Amgen's products. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. In addition, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for its products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations.

The scientific information discussed in this news release related to 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. 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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