Results Published in The Lancet Demonstrate Superiority of XGEVA(TM) (Denosumab) in the Prevention of Bone Complications for Men With Bone Metastases From Advanced Prostate Cancer

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Bone Is One of the Most Common Sites for Metastases Affecting up to 75 Percent of Patients with Advanced Prostate Cancer

THOUSAND OAKS, Calif., Feb. 24, 2011 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced the publication of results from a Phase 3 head-to-head trial that compared XGEVA**(TM)** (denosumab) to Zometa(R) (zoledronic acid) in preventing bone complications called skeletal-related events (SREs) in 1,901 men with prostate cancer and bone metastases. The study, published in *The Lancet*, met its primary and secondary endpoints and demonstrated XGEVA's superiority compared to Zometa in preventing SREs.

XGEVA was approved by the U.S. Food and Drug Administration (FDA) on Nov. 18, 2010 for the prevention of SREs in patients with bone metastases from solid tumors, including prostate cancer. XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma. XGEVA, the first and only FDA-approved RANK Ligand inhibitor, is the first new treatment for advanced cancer patients with bone metastases in nearly a decade.

"Bone metastases represent a significant risk for advanced prostate cancer patients due to the potential for serious bone complications such as fracture and spinal cord compression," said Karim Fizazi, M.D., Ph.D., head of the department of Medical Oncology, Institut Gustave-Roussy, Villejuif, France. "The results of this study show that XGEVA prevents these serious bone complications more effectively than Zometa without the requirement of intravenous infusion and without the need for dose adjustment for renal function. XGEVA represents an important new treatment option for advanced prostate cancer patients with bone metastases."

Bone metastases, the spread of cancer to the bones, are a serious concern for patients with advanced cancer and present a considerable burden to the healthcare system. Weakened bones due to metastases can lead to fractures and compression of the spinal cord and necessitate procedures including major surgery and radiation, designed to prevent or manage these bone complications. The primary goal of treatment for bone metastases is to prevent the occurrence of debilitating and costly bone complications, which can disrupt a patient's life and cause disability, pain and hospitalization.

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.

This study is one of three pivotal Phase 3 head-to-head trials comparing XGEVA to Zometa. In total, these studies, which formed the basis of the FDA's approval, enrolled over 5,700 patients with advanced cancer.

Study Results

An SRE consists of any of the following: fracture, radiation to bone, surgery to bone or spinal cord compression. All can be serious complications for advanced cancer patients. In this study, XGEVA was superior to Zometa in significantly delaying the time to first on-study SRE (hazard ratio 0.82, 95 percent CI: 0.71, 0.95; P = 0.008) with a median time to first on-study SRE of 20.7 months versus 17.1 months for Zometa. XGEVA was also superior to Zometa in significantly delaying the development of multiple SREs (time to first and subsequent on-study SRE) (hazard ratio 0.82, 95 percent CI: 0.71, 0.94; P = 0.008).

Overall rates of adverse events (AEs) and serious adverse events were generally similar between the two arms. Osteonecrosis of the jaw (ONJ) was infrequent, 22 patients receiving XGEVA (2 percent), as compared with 12 patients receiving Zometa (1 percent); the incidence of ONJ was not significantly different between treatment arms (P = 0.09). As with previous studies in advanced cancer patients, hypocalcemia was more frequent in the XGEVA arm. Overall survival and progression-free survival were similar between treatment arms. The most common AEs for XGEVA were anemia, back pain, and nausea, and the most common AEs for Zometa were anemia, back pain, and decreased appetite.

Study Design

Study "103" is an international, Phase 3, randomized, double-blind study comparing XGEVA with Zometa in the treatment of bone metastases in patients with advanced prostate cancer to prevent SREs. Patients enrolled in the study were randomized in a one-to-one ratio to receive either 120 mg of XGEVA subcutaneously every four weeks (Q4W) or Zometa administered intravenously at a dose of 4 mg in a 15 minute infusion every four weeks adjusted for renal function as per the Zometa label instructions. The study consisted of 1,901 patients with a median age of 71, who had bone metastases from castration resistant prostate cancer. The primary endpoint was time to first on-study SRE.

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.

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 for full prescribing information.

Denosumab is also marketed as Prolia(R) in other indications.

XGEVA Skeletal-Related Events Regulatory Status

XGEVA was approved by the FDA for the prevention of SREs in patients with bone metastases from solid tumors on Nov. 18, 2010. XGEVA is not indicated to prevent SREs in patients with multiple myeloma.

Administered as a single 120 mg subcutaneous injection every four weeks, XGEVA provides a new option for urologists and oncologists to prevent serious bone complications in men with prostate cancer.

Amgen has also submitted marketing applications for XGEVA in the European Union, Australia, Canada and Switzerland. In Japan, Amgen is working with its licensing partner, Daiichi-Sankyo Company, Limited and a marketing application was submitted.

Bone Metastases and Skeletal Related Events: Prevalence and Impact

Bone metastases occur in more than 1.5 million patients with cancer worldwide and are most commonly associated with cancers of the prostate, lung, and breast, with incidence rates as high as 75 percent of patients with metastatic disease.(i)

Approximately 50-70 percent of cancer patients with bone metastases will experience debilitating SREs.(ii)(iii)(iv) Events considered to be SREs include fractures, spinal cord compression, and severe bone pain that may require surgery or radiation.(v) Such events can profoundly disrupt a patient's life and can cause disability and pain.(vi)(vii)(viii)

Denosumab and Amgen's Research in Bone Biology

The denosumab development program demonstrates Amgen's commitment to researching and delivering pioneering medicines to patients with unmet medical needs. Amgen is studying denosumab in numerous tumor types across the spectrum of cancer-related bone diseases. Over 11,000 patients have been enrolled in the denosumab oncology clinical trials. In addition to this newly approved indication, XGEVA is also being investigated for its potential to delay bone metastases in prostate and breast cancer.

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, 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 vital medicines, visit www.amgen.com.

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. 24, 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 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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