FDA Approves Amgen's XGEVA(TM) (Denosumab) for the Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumors

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First Bone Targeted Therapy for Cancer Patients to Be Approved in Nearly a Decade
Approval Based on Largest Clinical Program Ever Conducted in Patients with Bone Metastases

THOUSAND OAKS, Calif., Nov. 18, 2010 /PRNewswire via COMTEX/ --

Amgen Inc. (Nasdaq: AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved XGEVA(TM) (denosumab), the first and only RANK Ligand inhibitorfor the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors. XGEVA was approved following a 6 month priority review by the FDA, a designation reserved for drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma.

"Today's approval of XGEVA illustrates what is possible when scientific innovation, commitment and investment come together to advance medicine," said Kevin Sharer, chairman and chief executive officer of Amgen. "A diagnosis of bone metastases is a major event for patients living with cancer, and the consequences can be devastating. We are pleased to offer this new advance to patients and their healthcare providers."

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 like major surgery and radiation, designed to prevent or manage 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.

"As many as 3 out of 4 patients with advanced prostate, lung, and breast cancer will experience spread to their bones. Despite the availability of current treatments, a significant proportion of these patients still experience bone complications or are not candidates for existing treatment," said David H. Henry, M.D., clinical professor of medicine, and vice chair, Department of Medicine, Pennsylvania Hospital, University of Pennsylvania Healthcare System. "Based on the compelling science and robust clinical evidence seen with XGEVA, I expect this new option to quickly become a mainstay of cancer care and to play an important role in reducing the incidence of debilitating bone complications in patients with advanced cancer."

The RANK Ligand pathway, first discovered by Amgen scientists in the mid-1990s, is believed to play a central role in cancer-induced bone destruction, regardless of cancer type. 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 fromactivating its receptor, RANK on the surface of osteoclasts, thereby decreasing bone destruction.

XGEVA Clinical Trial Experience

The FDA approval of XGEVA is based on the results of three pivotal, Phase 3 head-to-head trials that evaluated XGEVA delivered every four weeks as a 120 mg subcutaneous injection versus Zometa(R) (zoledronic acid) delivered every four weeks via a 15-minute intravenous infusion, adjusted for kidney function per the labeled instructions. The clinical program for XGEVA spanned more than 50 tumor types in over 5,700 patients. In the Phase 3 trials, XGEVA demonstrated a clinically meaningful improvement in preventing SREs compared to Zometa. Specifically, in patients with breast or prostate cancer and bone metastases, XGEVA was superior to Zometa in reducing the risk of SREs. In patients with bone metastasis due to other solid tumors or bone lesions due to multiple myeloma, XGEVA was noninferior (trending towards superiority) to Zometa in reducing the risk of SREs. Superiority was also seen in the integrated analysis of the Phase 3 studies.

Overall rates of adverse events and serious adverse events were generally similar between XGEVA and Zometa. Osteonecrosis of the jaw (ONJ) was infrequent, with no statistically significant difference between treatment arms. Hypocalcemia was more frequent in the XGEVA arm. Overall survival and progression-free survival were similar between arms in all three trials.

"As many as 70 percent of patients with prostate cancer that have metastasized to the bone are not currently receiving therapy to prevent complications from these bone metastases. This may be secondary to urologists lacking comfort or facilities to provide infusion treatment," said Neal D. Shore, M.D., FACS, medical director, Carolina Urologic Research Center. "XGEVA could provide increased treatment care options and accessibility for urologist's who treat advanced prostate cancer; as XGEVA is administered as a subcutaneous injection on a monthly basis. Also, XGEVA does not require dose adjustment for changes in renal function."

ECONOMIC IMPACT OF SREs

The total economic burden of patients with bone metastases in the U.S. alone estimated to be $12.6 billion annually.(i) Patients who experience an SRE as a result of bone metastases incur significantly higher medical costs compared with those who do not experience such events. (ii, iii, iv) In addition, once patients experience an SRE, the risk of a subsequent SRE is increased. The costs of SREs vary by type and severity, ranging from relatively low costs for minor fractures to high cost events like spinal cord compression associated with hospitalization. Studies have shown that the costs of treating SREs are a significant cost burden.

XGEVA is an innovative therapy that significantly reduces debilitating and costly SREs. This can result in cost offsets due to the reduced incidence of SREs and related medical costs. XGEVA will cost $1,650 monthly based on wholesale acquisition cost.

XGEVA FIRST STEP(TM) COUPON PROGRAM

Amgen is committed to supporting patient access to important medicines through innovative programs including our newly established commercial co-pay program for XGEVA, financial support to independent third party co-pay foundations, and the Safety Net Foundation, which provides free products to uninsured patients who qualify. The XGEVA FIRST STEP(TM) Coupon Program is a landmark program among oncology commercial

co-pay programs, as it is the first program under the medical benefit with no income eligibility requirement. The program is intended to provide assistance to eligible patients who need help meeting their deductible, co-insurance, and/or co-payment requirements under the medical benefit for XGEVA. Under this program, eligible patients will incur no out of pocket costs for their initial XGEVA injection and pay a maximum of $25 for subsequent injections.

XGEVA Regulatory Status

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 in August.

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 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 http://www.amgen.com/ for full prescribing information.

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

Bone Metastases and SREs: 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.(v)

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

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 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, 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, visithttp://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 Nov.18, 2010 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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