Amgen Receives CHMP Positive Opinion for XGEVA(TM) (Denosumab) in the European Union

May 20, 2011

Positive Opinion Based on Largest Clinical Program Ever Conducted in Patients with Bone Metastases

THOUSAND OAKS, Calif., May 20, 2011 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended a positive opinion for the marketing authorization of XGEVA(TM) (denosumab) for the prevention of skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumors. If approved by the European Commission, Amgen would receive marketing authorization for XGEVA in all European Union (EU) Member States. The CHMP also recommended to grant XGEVA an additional year of data and market exclusivity in the EU since the indication was considered significantly new for XGEVA, and based on the significant clinical benefit of the product in comparison with existing therapies.

Bone metastases, the spread of cancer to the bones, are a common and serious concern for patients with advanced cancer and present a 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, collectively called skeletal-related events (SREs). The primary goal of treatment for bone metastases is to prevent the occurrence of these debilitating and costly SREs.

"A diagnosis of skeletal-related events associated with bone metastases is devastating for patients living with cancer, and our goal is to prevent the occurrence of these debilitating bone complications, which can disrupt a patient's life and cause disability, pain, and hospitalization," said Willard Dere, M.D., senior vice president and international chief medical officer, Amgen. "XGEVA provides patients with superior efficacy over Zometa in preventing skeletal-related events in patients with solid tumors and prolonging the time until pain worsens. XGEVA also offers the ease of every four weeks subcutaneous injection and no requirement for dose adjustment for changes in renal function. XGEVA has the potential to make a meaningful difference for patients with advanced cancer and their healthcare providers."

The CHMP positive opinion is based on three pivotal, Phase 3 head-to-head trials that evaluated the effectiveness of XGEVA versus Zometa® (zoledronic acid) at delaying SREs. The clinical program for XGEVA spanned more than 50 tumor types in over 5,700 patients. In the SRE 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 metastases due to other solid tumors or multiple myeloma, XGEVA was non-inferior to Zometa in reducing the risk of SREs. In an integrated analysis of all three studies XGEVA was superior to Zometa in delaying time to first on-study SRE by 17 percent or 8.2 months (median time to first skeletal related event of 27.6 months for XGEVA and 19.4 months for Zometa, $p < 0.0001$). In this analysis, XGEVA was also superior to Zometa in delaying time to first-and-subsequent on-study SRE by 18 percent ($p<0.0001$).

In patients with mild or no pain at baseline, time to worsening pain was delayed for XGEVA compared to Zometa (198 versus 143 days) ($p=0.0002$). The time to pain improvement was similar for XGEVA and Zometa.

In these double-blind trials, XGEVA was administered every four weeks as a 120 mg subcutaneous injection, versus Zometa delivered every four weeks via a 15-minute intravenous infusion, with adjustments for kidney function per the requirements of the Zometa prescribing information. XGEVA was not associated with renal toxicity or acute phase reactions, both well known side effects of Zometa treatment.

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 treatment group. Overall survival and progression-free survival were similar between arms in all three trials.

XGEVA Regulatory Status

XGEVA is currently approved in the United States (U.S.) for the prevention of SREs in patients with bone metastases from solid tumors. XGEVA was approved following a six month priority review by the U.S. Food and Drug Administration (FDA). In the U.S., XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma.(i) XGEVA is also approved in Canada for reducing the risk of developing SREs in patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer, and other solid tumors. In Canada, XGEVA is not indicated for reducing the risk of developing SREs in patients with multiple myeloma.

Amgen has also submitted marketing applications for XGEVA in Australia, Mexico, Russia and Switzerland. In Japan, Amgen is working with its licensing partner, Daiichi Sankyo Company, Limited and a marketing application was submitted in August. 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 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 http://www.amgen.com/ for full U.S. prescribing information.

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 90 percent of patients with metastatic disease. (ii) (iii) (iv) (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 the prevention of SREs, XGEVA is also being evaluated 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, 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/.

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 May 20, 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 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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