Phase 3 Data Demonstrate XGEVA(TM) (Denosumab) is First Bone Targeted Therapy to Prevent Spread of Cancer to the Bone in Men With Advanced Prostate Cancer

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Study Meets Primary Endpoint by Significantly Improving Bone Metastasis-Free Survival for More Than Four Months
Up to 90 Percent of Men with Advanced Prostate Cancer Will Develop Bone Metastases

THOUSAND OAKS, Calif., May 17, 2011 /PRNewswire via COMTEX/ --

Amgen (NASDAQ: AMGN) today announced primary results of a pivotal Phase 3 trial ('147) demonstrating that XGEVA(TM) (denosumab) significantly increased bone metastasis-free survival for more than four months in men with castrate-resistant metastatic prostate cancer that has not yet spread to bone. Full results of the '147 study were presented for the first time today in a late-breaking plenary session at the American Urological Association (AUA) 2011 Annual Meeting in Washington, D.C.

With effective therapies now in place for both early (castrate-sensitive) prostate cancer and advanced (castrate-resistant) prostate cancer, there is a gap in the treatment plan for those patients who are castrate-resistant but have not yet developed metastatic disease. Bone is the most common place for prostate cancer to spread; up to 90 percent of men with prostate cancer will experience bone metastases.(i)(ii)(iii)

The data showed that 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 also 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), and the hazard ratio for progression-free survival was 0.89 (95 percent CI: 0.78, 1.02, P=0.093).

"In this landmark Phase 3 study, XGEVA increased bone metastasis-free survival by preventing bone metastases in men with castration-resistant prostate cancer," said Matthew Smith, M.D., Ph.D., director of the Genitourinary Malignancies Program at Massachusetts General Hospital Cancer Center, Boston. "XGEVA is the first and only bone targeted therapy that has demonstrated the ability to significantly reduce the risk of bone metastasis in men with prostate cancer."

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, multi-center 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 (castrate-resistant) prostate cancer with rapidly-rising prostate-specific antigen (PSA) levels who had no bone metastases at baseline. 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 the first and only RANK Ligand inhibitor approved by the U.S. Food and Drug Administration (FDA) indicated for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors. 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 skeletal-related events in patients with advanced cancer.

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 7,000 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 in adjuvant breast cancer.

XGEVA Skeletal-Related Events Regulatory Status

Amgen has submitted marketing applications for XGEVA in the European Union, Australia, and Switzerland for the prevention of SREs in patients with bone metastases from solid tumors. In Japan, Amgen is working with its licensing partner, Daiichi Sankyo Company, Limited and a marketing application was submitted.

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

Denosumab is also marketed as Prolia® in other indications.

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 prescribing information.

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 90 percent of patients with metastatic disease.(iv)(v)(vi)(vii)

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

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, 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 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 May 17, 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 statement related to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. FDA or the European Medicines Agency (EMA) 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, EMA or other applicable regulatory bodies can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the approved labeling for the products, and not the information discussed in this statement.

CONTACT: Amgen, Thousand Oaks
Christine Regan, 805-447-5476 (media)
Arvind Sood, 805-447-1060 (investors)

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