



Amgen Highlights Data to be Presented at 2011 European Multidisciplinary Cancer Congress

September 23, 2011

THOUSAND OAKS, Calif., Sept. 23, 2011 /PRNewswire via COMTEX/ -- Amgen (NASDAQ: AMGN) announced today that data from XGEVA® (denosumab) and Vectibix® (panitumumab) studies will be presented at the 2011 European Multidisciplinary Cancer Congress, Sept. 23 - 27, 2011, in Stockholm, Sweden.

"The data being presented at the 2011 European Multidisciplinary Cancer Congress reflect Amgen's ongoing commitment to advancing the understanding of cancer and developing novel therapies to treat it," said Willard H. Dere, M.D., senior vice president and international chief medical officer at Amgen. "New biomarker analyses for Vectibix reinforce the importance of patient selection when EGFR inhibitors are used in metastatic colorectal cancer, while data from the '147 study demonstrate the potential for XGEVA to be the first treatment to prevent the spread of prostate cancer to the bone."

SELECTED ABSTRACTS OF INTEREST

Identified below are selected abstracts of interest on Amgen research. Updated data will be presented at the meeting.

- **Denosumab and Bone Metastasis-free Survival in Men with Castrate-resistant Prostate Cancer: Subgroup Analyses From an International, Double-blind, Randomized, Phase 3 Trial**

(Abstract 7003) Proffered Papers Session Genitourinary Malignancies - Prostate Cancer on Sunday, Sept. 25, 9:45 a.m. CEST, Hall A3

Data embargoed until 12:01 a.m. CEST on Sept. 24. Data to be highlighted in EMCC press program on Sept. 24 at 8:00 a.m. CEST, Room K21 (Level 1).

- **Denosumab Treatment for Giant Cell Tumor of Bone (GCTB) in Adolescent Patients: Interim Results from a Phase 2 Study**

(Abstract 32LBA) Proffered Papers Session, Sarcoma on Tuesday, Sept. 27, 11:00 a.m. CEST, Hall T2

- **Pain Outcomes in a Randomized Phase 3 Clinical Trial of Denosumab vs Zoledronic Acid (ZA) in Patients with Solid Tumors and Bone Metastases**

(Abstract 7004) Proffered Papers Session Genitourinary Malignancies - Prostate Cancer on Sunday, Sept. 25, 9:55 a.m. CEST, Hall A3

- **Safety and Efficacy of Panitumumab (pmab) in HPV Positive (+) and HPV Negative (-) Recurrent/Metastatic (R/M) Squamous Cell Carcinoma of the Head and Neck (SCCHN): Analysis of the Phase 3 SPECTRUM Trial**

(Abstract 25LBA) Proffered Papers Session Head and Neck Cancer on Saturday, Sept. 24, 13:20 (1:20 p.m.) CEST, Hall K1

- **Evaluation of Individual Codon 12 and 13 Mutant (MT) KRAS Alleles as Prognostic and Predictive Biomarkers of Response to Panitumumab (pmab) in Patients With Metastatic Colorectal Cancer (mCRC)**

(Abstract 33LBA) Proffered Paper Session Personalized Medicine on Sunday, Sept. 25, 10:30 a.m. CEST, Victoria Hall

ADDITIONAL XGEVA ABSTRACTS

- **Health Resource Utilization (HRU) Associated with Skeletal-related Events (SREs) by Tumor Type in Patients with Bone Metastases/lesions: European Analysis of a Prospective Multinational Observational Study**

(Abstract 3613) Poster Session on Saturday, Sept. 24, 9:30 a.m. - 12:00 p.m. CEST

- **Effect of Denosumab Treatment on Prevention of Hypercalcemia of Malignancy in Cancer Patients with Metastatic Bone Disease**

(Abstract 3051) Poster Session on Monday, Sept. 26, 9:30 a.m. - 12:00 p.m. CEST

- **Prevention of Skeletal-Related Events with Denosumab or Zoledronic Acid - Combined Analysis From 3 Registrational Trials**

(Abstract 3061) Poster Session on Monday, Sept. 26, 9:30 a.m. - 12:00 p.m. CEST

ADDITIONAL VECTIBIX ABSTRACTS

- **Efficacy of Panitumumab Plus FOLFIRI Versus FOLFIRI Alone in Patients with Wild-type (WT) KRAS Metastatic Colorectal Cancer (mCRC) Treated with Prior Oxaliplatin or Bevacizumab Regimens: Results from 20050181.**

(Abstract 6132) Poster Session on Sunday, Sept. 25, 9:30 a.m. - 12:00 p.m. CEST

Study 20050203/PRIME: Effect of Post-Progression Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody (mAb) Therapy in Patients (pts) with Wild-type (WT) KRAS Metastatic Colorectal Cancer (mCRC)

(Abstract 6143) Poster Session on Sunday, Sept. 25, 9:30 a.m. - 12:00 p.m. CEST

Randomized, Open-label, Phase 3 Study of Panitumumab (pmab) with FOLFOX4 vs FOLFOX4 Alone as 1st-line Treatment for Metastatic Colorectal Cancer (mCRC): the Role of Hypomagnesemia (hypomag) on Efficacy

(Abstract 6095) Poster Session on Sunday, Sept. 25, 9:30 a.m. - 12:00 p.m. CEST

Abstracts are available on the EMCC website at <http://stockholm2011.ecco-org.eu/Programme.aspx>. Late breakers and any abstracts that form part of the EMCC media programme will be posted on the day of presentation.

About XGEVA

XGEVA is the first and only RANK Ligand inhibitor approved by the FDA indicated for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors. XGEVA was 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. XGEVA is delivered as an every four week 120 mg subcutaneous injection and is not associated with renal toxicity or acute phase reactions.

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 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 Important Safety Information

XGEVA can cause severe hypocalcemia. Correct pre-existing hypocalcemia prior to XGEVA treatment. Monitor calcium levels in patients at greater risk of developing hypocalcemia. Administer calcium and vitamin D in all patients (unless hypercalcemia is present). 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.

Adverse reactions in patients receiving XGEVA included fatigue/asthenia, hypophosphatemia, nausea, dyspnea and diarrhea.

Please visit <http://www.amgen.com/> for full U.S. prescribing information.

XGEVA Skeletal-Related Events Regulatory Status

The European Commission (EC) granted a Marketing Authorization for XGEVA for the prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumors. As part of the review, the EC also granted XGEVA one additional year of marketing protection based on the indication being considered new for denosumab and the significant clinical benefit offered by the product in comparison with existing therapies.

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 Mexico, Russia, and Switzerland. In Japan, Amgen is working with its licensing partner, Daiichi Sankyo Company, Limited and a marketing application was submitted. 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.

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

About Vectibix

Vectibix injection for IV infusion is the first fully human anti-EGFR antibody approved by the U.S. Food and Drug Administration (FDA) for the treatment of mCRC. Vectibix received accelerated approval in the U.S. in September 2006 as a monotherapy for the treatment of patients with EGFR-expressing mCRC after disease progression on or following fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy regimens.

The effectiveness of Vectibix as a single agent for the treatment of EGFR-expressing mCRC is based on progression-free survival. Currently no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

Retrospective subset analyses of mCRC trials have not shown a treatment benefit for Vectibix in patients whose tumors had KRAS mutations in codon 12 or 13. Use of Vectibix is not recommended for the treatment of mCRC with these mutations.

In December 2007, the European Commission granted a conditional marketing authorization for Vectibix as a monotherapy for the treatment of patients with EGFR expressing mCRC with non-mutated (wild-type) KRAS after failure of fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy regimens. Vectibix has been launched in more than 40 countries worldwide.

Important U.S. Product Safety Information

WARNING: DERMATOLOGIC TOXICITY and INFUSION REACTIONS

Dermatologic Toxicity: Dermatologic toxicities occurred in 89 percent of patients and were severe (NCI-CTC grade 3 or higher) in 12 percent of patients receiving Vectibix monotherapy. [See Dosage and Administration (2.1), Warnings and Precautions (5.1), and Adverse Reactions (6.1)].

Infusion Reactions: Severe infusion reactions occurred in approximately one percent of patients. Fatal infusion reactions occurred in postmarketing experience [See Dosage and Administration (2.1), Warnings and Precautions (5.2), and Adverse Reactions (6.1, 6.3)].

The most common adverse events of Vectibix are skin rash with variable presentations, hypomagnesemia, paronychia, fatigue, abdominal pain, nausea, and diarrhea, including diarrhea resulting in dehydration.

Important European Product Safety Information

For full prescribing information please see the Summary of Product Characteristics.

Vectibix is indicated as monotherapy for the treatment of patients with EGFR expressing, mCRC with non-mutated (wild-type) *KRAS* after failure of fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy regimens.

Vectibix is contraindicated in patients with a history of severe or life-threatening hypersensitivity reactions to the product and in patients with interstitial pneumonitis or pulmonary fibrosis.

Other adverse events of special importance associated with Vectibix and/or EGFR monoclonal antibody therapies include dermatologic related reactions, pulmonary complications, electrolyte disturbances and infusion related reactions (including rare reports with fatal outcome). Acute renal failure has been observed in patients who develop severe diarrhea and dehydration. Serious cases of keratitis and ulcerative keratitis have been rarely reported in the post-marketing setting. These events should be monitored carefully, see Summary of Product Characteristics for information on appropriate management of these adverse events.

Vectibix should not be used in combination with IFL chemotherapy or in combination with bevacizumab-containing chemotherapy.

Vectibix should not be administered in combination with oxaliplatin-containing chemotherapy to mCRC patients with mutant *KRAS* tumors or for whom *KRAS* tumor status is unknown.

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/>. Follow us on <http://twitter.com/amgen>.

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 Sept. 23, 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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