Amgen Oncology Data to be Presented at ASCO Annual Meeting

May 18, 2011

THOUSAND OAKS, Calif., May 18, 2011 /PRNewswire via COMTEX/ --

Amgen (NASDAQ: AMGN) today announced that data from studies involving nine Amgen products will be presented at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting, June 3 - 7, 2011 in Chicago. These studies include data from the XGEVA® (denosumab), Vectibix® (panitumumab), ganitumab (AMG 479) and AMG 386 programs.

"Amgen researchers around the globe are passionate about developing new and innovative therapies for patients with cancer," said Sean Harper, M.D., Amgen senior vice president, global development and corporate chief medical officer. "The data that will be presented at this year's ASCO meeting further define the clinical profile of XGEVA in cancer patients with bone metastases from solid tumors and of Vectibix in patients with metastatic colorectal cancer, as well as provide important insights into the benefit-risk profiles of several of our pipeline molecules."

Abstracts are available on the ASCO website at http://abstract.asco.org/.

SELECTED XGEVA ABSTRACTS

- **Effect of denosumab vs. zoledronic acid in patients with castrate-resistant prostate cancer and bone metastases: Subgroup analyses by prior SRE and baseline pain**

(Abstract 4533) Poster Discussion on Saturday, June 4, 2:00 p.m. - 6:00 p.m., E450a

- **Prevalence of recognized bone metastases in the U.S. adult population**

(Abstract 1534) Poster on Saturday, June 4, 2:00 p.m. - 6:00 p.m., Hall A

- **Denosumab safety and efficacy in giant cell tumor of bone (GCTB): Interim results from a phase II study**

(Abstract 10034) Poster on Sunday, June 5, 8:00 a.m. - 12:00 p.m., Hall A

- **Effects of denosumab on pain reduction in giant cell tumor of bone (GCTB): interim phase II study results**

(Abstract 10037) Poster on Sunday, June 5, 8:00 a.m. - 12:00 p.m., Hall A

- **A randomized, double-blind, placebo-controlled multicenter phase III study comparing denosumab with placebo as adjuvant treatment for women with early-stage breast cancer who are at high risk of disease recurrence (D-CARE)**

(Abstract TPS152) Poster on Monday, June 6, 8:00 a.m. - 12:00 p.m., Hall A

- **A single-arm multicenter proof-of-concept study of denosumab to treat hypercalcemia of malignancy in patients who are refractory to IV bisphosphonates**

(Abstract TPS245) Poster on Monday, June 6, 8:00 a.m. - 12:00 p.m., Hall A

SELECTED VECTIBIX ABSTRACTS

- **Final results from PRIME: Randomized phase III study of panitumumab (pmab) with FOLFOX4 for first-line metastatic colorectal cancer(mCRC)**

(Abstract 3510) Oral Presentation on Saturday, June 4, 1:00 p.m. - 4:00 p.m., Hall D1

- **Randomized phase III study of panitumumab (pmab) with FOLFOX4 compared with FOLFOX4 alone as first-line treatment (tx) for metastatic colorectal cancer (mCRC): Results by Eastern Cooperative Oncology Group (ECOG) performance status (PS)**

(Abstract 3567) Poster on Saturday, June 4, 8:00 a.m. - 12:00 p.m., Hall A

- **Evaluating the relationship between progression-free survival (PFS) and overall survival (OS) in clinical trials of patients (pts) with metastatic colorectal cancer(mCRC)**

(Abstract 3617) Poster on Saturday, June 4, 8:00 a.m. - 12:00 p.m., Hall A

- **Evaluation of panitumumab (pmab) plus fluorouracil, leucovorin and irinotecan (FOLFIRI) after first-line bevacizumab (bev) in patients (pts) with metastatic colorectal cancer (mCRC): A subgroup analysis of study 181**

(Abstract 3574) Poster on Saturday, June 4, 8:00 a.m. - 12:00 p.m., Hall A

- **The relationship between quality of life (QOL) and tumor response in patients (pts) with metastatic colorectal cancer (mCRC) receiving panitumumab (pmab) plus FOLFIRI as first-line therapy: An analysis of study 314**

(Abstract 3634) Poster on Saturday, June 4, 8:00 a.m. - 12:00 p.m., Hall A

- **Evaluation of gene mutations beyond *KRAS* as predictive biomarkers of response to panitumumab in a randomized, phase III monotherapy study of metastatic colorectal cancer(mCRC)**

(Abstract 3530) Poster Discussion on Monday, June 6, 8:00 a.m. - 12:00 p.m., E450b

SELECTED ARANESP® (darbepoetin alfa) ABSTRACTS

- **Survival effect of darbepoetin alfa in patients with diffuse large B-cell lymphoma (DLBCL) treated with immunochemotherapy: The LNH03-6B study**

(Investigator Sponsored Abstract 9048) Saturday, June 4, 2:00 p.m. - 6:00 p.m., Hall A

SELECTED PIPELINE ABSTRACTS

- **A randomized, phase Ib/II trial of rilotumumab (AMG 102; ril) or ganitumab (AMG 479; gan) with panitumumab (pmab) versus pmab alone in patients (pts) with wild-type (WT) KRAS metastatic colorectal cancer (mCRC): Primary and biomarker analyses**

(Abstract 3500) Oral Presentation on Saturday, June 4, 4:30 p.m. - 6:00 p.m., Hall D1

- **Effect of baseline (BL) biomarkers on overall survival (OS) in metastatic pancreatic cancer (mPC) patients (pts) with ganitumab (GAN, AMG 479) or placebo (P) in combination with gemcitabine (G)**

(Abstract 4041) Poster on Saturday, June 4, 8:00 a.m. - 12:00 p.m., Hall A

- **Exposure-response (E-R) analysis to facilitate phase III dose selection for ganitumab (GAN, AMG 479) in combination with gemcitabine (G) to treat metastatic pancreatic cancer(mPC)**

(Abstract 4049) Poster on Saturday, June 4, 8:00 a.m. - 12:00 p.m., Hall A

- **A randomized, placebo-controlled phase II study of AMG 386 plus bevacizumab (Bev) and paclitaxel (P) or AMG 386 plus P as first-line therapy in patients (pts) with HER2-negative, locally recurrent or metastatic breast cancer(LR/MBC)**

(Abstract 544) Poster on Monday, June 6, 1:00 p.m. - 5:00 p.m., Hall A

- **An international, randomized, placebo-controlled, double-blind phase III study (MONET1) of motesanib plus carboplatin/paclitaxel (C/P) in patients with advanced nonsquamous non-small cell lung cancer (NSCLC)**

(Abstract LBA7512) Poster Discussion on Monday, June 6, 2:00 p.m. - 6:00 p.m., E450a

For the latest updates on Amgen's presence at ASCO and other Amgen news, follow us on Twitter @Amgen.

About XGEVA

XGEVA is the first and only RANK Ligand inhibitor approved by the U.S. Food and Drug Administration (FDA) that is 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 patients with advanced cancer 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 SREs 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.

The clinical program for XGEVA spanned more than 50 tumor types in more than 5,700 patients. 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 advanced prostate cancer and adjuvant breast cancer.

Amgen has 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.

For more information on XGEVA, please visit www.XGEVA.com.

Denosumab is also marketed as Prolia® in other indications.

Important U.S. XGEVA Product 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 (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.

About Vectibix

Vectibix is the first fully human anti-EGFR antibody approved by the FDA for the treatment of mCRC. Vectibix was approved 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 colorectal cancer with these mutations.

In December 2007, the European Medicine Agency (EMA) 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 30 European Union countries, Russia, Israel, Switzerland, Australia, Canada and Japan.

Applications in the rest of the world are pending.

Important U.S. Vectibix 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 1 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 Vectibix 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, metastatic colorectal carcinoma (mCRC) with nonmutated (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 common 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). These events should be monitored carefully, see Summary of Product Characteristics for information on appropriate management of these adverse events. Acute renal failure has been observed in patients who develop severe diarrhoea and dehydration.

Vectibix should not be used in combination with IFL [bolus 5-fluorouracil (500 mg/m2), leucovorin (20 mg/m2) and irinotecan (125 mg/m2)] or in combination with bevacizumab containing chemotherapy.

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

About Aranesp

Aranesp was approved by the FDA in 2001 for the treatment of anemia associated with chronic renal failure (CRF) for patients on dialysis and patients not on dialysis. The European Commission granted marketing authorization for the same indication in 2001 and subsequently updated it for CRF patients with symptomatic anemia in 2008.

In 2002, the FDA approved Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with nonmyeloid malignancies.

The European Commission authorized the treatment of anemia caused by concomitantly administered chemotherapy in patients with non-haematological malignancies in 2002 and extended it to include non-myeloid malignancies in patients receiving chemotherapy in 2003.

Important U.S. Aranesp Product Safety Information

Aranesp is indicated for the treatment of anemia due to the effect of concomitantly administered chemotherapy based on studies that have shown a reduction in the need for red blood cell transfusions in patients with metastatic, non-myeloid malignancies. Studies to determine whether Aranesp increases mortality or decreases progression-free/recurrence-free survival are ongoing.

- **Aranesp is not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy.**
- **Aranesp is not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure due to the absence of studies that adequately characterize the impact of Aranesp on progression-free and overall survival.**
- **Aranesp use has not been demonstrated in controlled clinical trials to improve symptoms of anemia, quality of life, fatigue, or patient well-being.**

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR EVENTS, THROMBOEMBOLIC EVENTS, STROKE AND INCREASED RISK OF TUMOR PROGRESSION OR RECURRENCE

Cancer:

- **ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.**
- **To decrease these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusion.**
- **Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense Aranesp, EPOGEN® or PROCRIT® to patients with cancer. To enroll in the ESA APPRISE Oncology Program, visit http://www.esa-apprise.com/ or call 1-866-284-8089 for further assistance.**
- **Use ESAs only for treatment of anemia due to concomitant myelosuppressive chemotherapy.**
- **ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure.**
- **Discontinue following the completion of a chemotherapy course.**
- **ESAs are contraindicated in patients with uncontrolled hypertension.**

Important European Aranesp Product Safety Information

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

Aranesp is indicated for treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.

Aranesp is contraindicated in patients with poorly controlled hypertension.

Controlled clinical trials have not shown significant benefits attributable to the administration of epoetins when haemoglobin concentration is increased beyond the level necessary to control symptoms of anaemia and to avoid blood transfusion.

In controlled clinical studies, use of Aranesp and other ESAs have shown:

- **shortened time to tumour progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target Hb > 14 g/dL; ESAs are not indicated for use in this patient population**
- **shortened overall survival and increased deaths attributed to disease progression at 4 months in patients with metastatic breast cancer receiving chemotherapy when administered to target Hb 12-14 g/dL**
- **increased risk of death when administered to target Hb of 12 g/dl (7.5 mmol/l) in patients with active malignant disease receiving neither chemotherapy nor radiation therapy; ESAs are not indicated for use in this patient population.**

In some clinical situations blood transfusion should be the preferred treatment for the management of anaemia in patients with cancer. The decision to administer recombinant erythropoietins should be based on a benefit-risk assessment with the participation of the individual patient, which should take into account the specific clinical context. Factors that should be considered in this assessment should include the type of tumour and its stage; the degree of anaemia; life-expectancy; the environment in which the patient is being treated; and patient preference.

In patients with solid tumours or lymphoproliferative malignancies, if Hb >12 g/dL, the dose should be reduced/held to minimise the potential risk of thromboembolic events.

Discontinue use after the end of chemotherapy.

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 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 18, 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 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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