

## Amgen Highlights Key Clinical Data to Be Presented at American Society of Clinical Oncology Annual Meeting

May 20, 2010

# First Presentation of Results from a Pivotal, Phase 3 Head-to-Head Denosumab Bone Metastases Advanced Prostate Cancer Trial

# First Integrated Analysis from Two Phase 3 Head-to-Head Denosumab Trials in Advanced Cancer Patients (Breast Cancer and Solid Tumors including Multiple Myeloma)

## First Presentations of Phase 2 Data from AMG 479 in Pancreatic Cancer and AMG 386 in Ovarian Cancer

THOUSAND OAKS, Calif., May 20, 2010 /PRNewswire via COMTEX/ --Amgen (Nasdaq: AMGN) today announced that results from studies involving nine molecules in the Company's oncology portfolio will be presented at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting, June 4- 8, 2010 in Chicago.

"Cancer is a complex disease that requires a comprehensive approach. Our goal is to help patients battle cancer by leveraging our understanding of cancer biology and pharmacogenomics to develop more targeted therapies, while building on our legacy of discovering and delivering supportive care products that help lessen the side effects of cancer treatment," said Sean Harper, M.D., chief medical officer of Amgen. "The data presented at this year's ASCO Annual Meeting demonstrate Amgen's commitment towards this goal."

Abstracts are available on the ASCO website at http://abstract.asco.org/ and updated data will be presented at the meeting.

## SELECTED ABSTRACTS OF INTEREST

## Denosumab

### Denosumab versus zoledronic acid for treatment of bone metastases in patients with castration-resistant prostate cancer

(Late Breaking Abstract Number 4507; Oral Presentation; June 6, 10:30 a.m., E Hall D2)

The first presentation of results of this international Phase 3, randomized, double-blind study comparing denosumab to Zometa(R) (zoledronic acid) in the treatment of bone metastases in patients with advanced prostate cancer. This is the final of three pivotal trials in a total of more than 5,700 advanced cancer patients investigating the potential of denosumab to treat bone metastases. Bone metastases, cancer cells that separate from tumors and migrate to bone tissue where they settle and grow, occur in more than 1.5 million people worldwide. These data are under embargo and will be presented in an oral session at the meeting.

## A meta-analysis of results from two randomized, double-blind studies of denosumab versus zoledronic acid (ZA) for treatment of bone metastases

(Abstract Number 9015; Oral Presentation; June 5, 5:15 p.m., E 354b)

An integrated analysis of two previously reported, identically designed head-to-head Phase 3 trials demonstrated denosumab treatment was superior to Zometa in delaying or preventing skeletal-related events (SREs) in a broad population of patients with advanced malignancies involving bone. These trials evaluated patients with breast cancer and other solid tumors (excluding breast or prostate cancer) or multiple myeloma, respectively. Overall rates of disease progression, survival, adverse events and serious adverse events were similar in both groups.

## Effects of denosumab versus zoledronic acid (ZA) on pain in patients (pts) with metastatic breast cancer: Results from a phase III clinical trial

(Abstract Number 1024; Poster Board: June 5, 12:00 p.m. - 1:00 p.m., E Hall D1, 13)

A combination of pre-specified and post-hoc analyses of a Phase 3 head-to-head study showed denosumab significantly extended the time breast cancer patients had no or mild pain, when compared to Zometa, with fewer denosumab patients experiencing worsening of pain. Overall adverse events rates were similar in both groups.

## Effects of denosumab versus zoledronic acid (ZA) on pain in patients (pts) with advanced cancer (excluding breast and prostate) or multiple myeloma (MM): Results from a randomized phase III clinical trial

(Abstract Number 9043; Poster Board: June 7, 1:00 p.m. - 5:00 p.m., S Hall A2, 39B)

A combination of pre-specified and post-hoc analyses of a Phase 3 head-to-head study showed denosumab prolonged time to worsening of pain compared with Zometa. In addition, among patients with no/mild pain at baseline, fewer denosumab-treated patients reported moderate/severe pain than Zometa-treated patients. Overall adverse event rates were similar in both groups.

## Delaying skeletal-related events in a randomized phase III study of denosumab versus zoledronic acid in patients with advanced cancer

(Abstract Number 9133; Poster Board; June 7, 1:00 p.m. - 5:00 p.m., S Hall A2, 51B)

A post-hoc subset analysis comparing the treatment effect in only patients with solid tumors (other than breast cancer or prostate cancer) and bone metastases showed that denosumab delayed or prevented SREs more effectively than Zometa. Both treatment groups had similar rates of overall survival, disease progression and overall adverse events.

## Denosumab in the treatment of bone metastases from advanced cancer or multiple myeloma (MM): Analyses from a phase III randomized trial

(Abstract Number 9042; Best of ASCO Poster Board: June 7, 1:00 p.m. - 5:00 p.m., S Hall A2, 39A)

In an exploratory analysis from a head-to-head study, patients receiving denosumab had longer time to first skeletal related event (SRE) or hypercalcemia of malignancy (HCM) and time to radiation to bone compared with Zometa. Also a lower proportion of patients experienced an on-study SRE in the denosumab group compared with Zometa.

## Effects of denosumab versus zoledronic acid (ZA) on health-related quality of life (HRQL) in metastatic breast cancer: Results from a randomized phase III trial

(Abstract Number 1025; Poster Discussion; June 5, 8:00 a.m. - 12:00 p.m., E450b)

In bone metastases secondary to breast cancer, patients receiving denosumab or zoledronic acid showed improvement or maintenance in healthrelated quality of life (HRQL) relative to baseline, while a greater proportion of denosumab-treated patients reported a clinically meaningful improvement in HRQL. Potential benefits of subcutaneous delivery of denosumab on HRQL were not captured since both treatment arms received subcutaneous and IV administration.

An additional four abstracts evaluating the impact of bone metastases, including health economic outcomes, will be presented at the meeting.

#### Pipeline

In addition to the denosumab data, fifteen studies across five molecules in the Amgen therapeutic pipeline will be presented. Selected presentations include:

## A placebo-controlled, randomized Phase 2 study of conatumumab or AMG 479, or placebo plus gemcitabine in patients with metastatic pancreatic cancer

(Abstract Number: 4035; Poster Discussion: June 4, 2:00 p.m. - 6:00 p.m., E450b; 23)

AMG 479 in relapsed or refractory Ewing's family tumors or desmoplastic small round cell tumors: Phase 2 results

(Abstract Number: 10001; Oral Presentation: June 7, 1:15 p.m., S406)

Primary analysis from a randomized, double-blind, placebo-controlled Phase 2 study of AMG 386 in combination with paclitaxel in patients with advanced ovarian cancer

(Abstract Number: 5000; Oral Presentation: June 7, 9:45 a.m., E Arie Crown Theater)

Biomarkers as predictors of response to treatment with motesanib or bevacizumab in combo with paclitaxel in patients with locally recurrent or metastatic breast cancer

(Abstract Number: 1048; Poster Board: June 5, 2:00 p.m. - 6:00 p.m., S Hall A2, 23A)

Placental growth factor as a marker of therapeutic response to treatment with motesanib in patients with progressive advanced thyroid cancer, advanced nonsquamous non-small cell lung cancer, and locally recurrent or advanced metastatic breast cancer

(Abstract Number: 3037; Poster Board: June 7, 8:00 a.m. - 12:00 p.m., S Hall A2, 10G)

## **Marketed Products**

Twelve abstracts will be presented on Vectibix(R) (panitumumab), including use in combination with chemotherapy for the treatment of metastatic colorectal cancer (mCRC). Selected presentations include:

Randomized, open label, phase III study of panitumumab (pmab) with FOLFOX4 versus FOLFOX4 alone as first-line treatment (tx) for metastatic colorectal cancer (mCRC): Efficacy by skin toxicity (ST) (Abstract Number: 3538; Poster Discussion: June 8, 11:00 a.m. to 12:00 p.m., S Hall 406 (Vista Room), IE) Randomized, open label, phase III study of panitumumab (pmab) with FOLFIRI versus FOLFIRI alone as second-line treatment (tx) in patients (pts) with metastatic colorectal cancer (mCRC): Efficacy by skin toxicity (ST) (Abstract Number 3529; Poster Discussion: June 8, 11:00 a.m. to 12:00 p.m., S Hall 406 (Vista Room), 20) SPIRITT: A multicenter, open-label, randomized, phase II clinical trial evaluating safety and efficacy of FOLFIRI with either panitumumab or bevacizumab as second-line treatment in patients with metastatic colorectal cancer (mCRC) with wild-type KRAS tumors (Abstract Number: TPS195; Poster Board: June 7, 8:00 a.m. to 12:00

PEAK: A randomized phase II study to compare the efficacy of panitumumab plus mFOLFOX6 to bevacizumab plus mFOLFOX6 in patients (pts) with previously untreated, unresectable,
metastatic colorectal cancer (mCRC) expressing wild-type KRAS (Abstract Number: TPS189; Poster Board: June 7, 8:00 a.m. to 12:00 p.m., S Hall A2)

#### Five abstracts will be presented on Neulasta(R)(pegfilgrastim), including:

A phase III randomized, double-blind, placebo-controlled study of pegfilgrastim in first-line colorectal cancer patients
-- receiving bevacizumab and either FOLFOX or FOLFIRI
(Abstract Number: TPS326; Poster Board: June 7, 8:00 a.m. to 12:00 p.m., S Hall A2)
Estimation of the U.S. rate of neutropenic complications for

-- cancer hospital discharges. (Abstract Number: 6027; Poster Discussion: June 5, 12:00 p.m. to 1:00 p.m., S Hall 504, 19)

### Seven abstracts will be presented on Aranesp(R) (darbepoetin alpha), including:

Design of an ongoing randomized study on the long-term safety and efficacy of darbepoetin alfa (DA) administered 500 mcg every three weeks (Q3W) to non-small cell lung cancer (NSCLC) patients -- (pts) with anemia concomitant with chemotherapy (ACC) (Abstract Number: TPS325; Poster Board: June 7, 8:00 a.m. to 12:00 p.m., S Hall A2, 44B) An exploratory analysis of transfusion risk when initiating darbepoetin alfa (DA) therapy at baseline hemoglobin (Hb) < 9 g/ dl vs 9 to < 10 g/dl vs > = 10 g/dl in patients (pts) with -- chemotherapy-induced anemia (CIA) (Abstract Number: 9077; Poster Board: June 7, 1:00 p.m. to 5:00 p.m., S Hall A2, 448)

Amgen will launch its newly designed *AmgenOncology.com* website at ASCO this year. The site features innovative user design, award-winning science video, as well as the Chemotherapy Guide PDA download, and all the latest highlights on Amgen Oncology Science. For the latest updates on Amgen's presence at ASCO and other Amgen news follow us on Twitter, @Amgen.

#### About Denosumab and Amgen's Research in Bone Biology

Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, the essential regulator of osteoclasts (the cells that break down bone). The denosumab development program is the largest ever initiated by Amgen. This broad and deep 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, testing the drug for the reduction of SREs in patients with breast and prostate cancer, as well as other solid tumors and multiple myeloma, for the amelioration of treatment-induced bone loss in patients with non-metastatic breast or prostate cancers, and for its potential to delay bone metastases in prostate cancer.

## **About Vectibix**

Vectibix is the first fully human anti-EGFR antibody approved by the United States (U.S.) Food and Drug Administration (FDA) for the treatment of mCRC. Vectibix was approved in the U.S. in September 2006 as monotherapy for the treatment of patients with EGFR-expressing metastatic colorectal carcinoma 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, metastatic colorectal carcinoma 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 metastatic colorectal cancer 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 Medicines Agency (EMA) granted a conditional marketing authorization for Vectibix as monotherapy for the treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) KRAS after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. Vectibix has been launched in over 20 EU countries, Russia, Israel, Switzerland, Australia and Canada. Applications in the rest of the world are pending.

## Important Vectibix 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.

Infusion Reactions: Severe infusion reactions occurred in approximately 1 percent of patients. Although not reported with Vectibix, fatal infusion reactions have occurred with other monoclonal antibody products.

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.

The most serious adverse events of Vectibix are pulmonary fibrosis, pulmonary embolism, severe dermatologic toxicity complicated by infectious sequelae and septic death, infusion reactions, abdominal pain, hypomagnesemia, nausea, vomiting, and constipation.

### About Neulasta

Neulasta was approved by the U.S. FDA in 2002 for decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with clinically significant incidence of febrile neutropenia. Similar indications for Neulasta were approved in Europe and Australia the same year.

### Important Neulasta Safety Information

Do not administer Neulasta to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.

Splenic rupture (including fatal cases), acute respiratory distress syndrome, and sickle cell crises have been reported. Allergic reactions, including anaphylaxis, have also been reported. The majority of allergic reactions occurred upon initial exposure. However, in rare cases, allergic reactions, including anaphylaxis, recurred within days after discontinuing antiallergic treatment.

Bone pain and pain in extremity occurred at a higher incidence in Neulasta-treated patients as compared with placebo-treated patients.

### **Important Aranesp 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 RBC 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.

## 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, 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, 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 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 products. 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. 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 not approved for the products for these uses. Only the FDA can determine whether 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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