



## Amgen to Present Pivotal Data From Four Phase 3 Studies at the ECCO 15 - ESMO 34 Congress

September 16, 2009

### Key Denosumab and Vectibix(R) (Panitumumab) Data to be Presented

THOUSAND OAKS, Calif., Sept. 16 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) today announced it will present detailed data from four Phase 3 studies as well as other data at the ECCO 15 - ESMO 34 European Multidisciplinary Congress, September 20 - 24, 2009 in Berlin, Germany.

Researchers will present data from two Phase 3 head-to-head studies evaluating denosumab versus Zometa(R) (zoledronic acid) for the treatment of bone metastases in patients with advanced breast cancer (the '136' study) and the treatment of bone metastases in advanced cancer patients with solid tumors (not including breast and prostate cancer) or multiple myeloma (the '244' study).

Detailed data will also be presented from two Phase 3 studies evaluating Vectibix(R) (panitumumab) in combination with chemotherapy for the first-line and second-line treatment of metastatic colorectal cancer (the '203' and '181' trials, respectively).

"Amgen is very pleased to be presenting these important data from the denosumab and Vectibix development programs," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "The data from these trials demonstrate that both denosumab and Vectibix have the potential to improve outcomes in patients suffering from cancer."

#### SELECTED ABSTRACTS OF INTEREST

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

##### Denosumab

-- A double-blind, randomized study of denosumab versus zoledronic acid for the treatment of bone metastases in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma

Lead Author: Henry, D.

Abstract No. 20LBA (Monday, Sept. 21, 2009, 12:45 -13:00 CEST)

-- Denosumab versus zoledronic acid for the treatment of breast cancer patients with bone metastases: Results of a randomized Phase 3 study

Lead Author: Stopeck, A.

Abstract No. 2LBA (Tuesday, Sept. 22, 2009, 14:15 - 14:30 CEST)

-- Overall survival in men with and without prevalent vertebral fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer

Lead Author: Smith, M.

Abstract No. 7005 (Monday, Sept. 21, 2009, 12:15 -12:45 CEST)

##### Vectibix

-- Randomized Phase 3 study of panitumumab with FOLFIRI vs FOLFIRI alone as second-line treatment (tx) in patients (pts) with metastatic colorectal cancer (mCRC)

Lead Author: Peeters, M.

Abstract No. 14LBA (Tuesday, Sept. 22, 2009, 10:45 - 11:00 CEST)

-- Randomized Phase 3 study of panitumumab with FOLFOX compared to FOLFOX alone as first-line treatment (tx) for metastatic colorectal cancer (mCRC): The PRIME trial

Lead Author: Douillard, J.Y.

Abstract No. 10LBA (Thursday, Sept. 24, 2009, 11:00 - 11:15 CEST)

An analyst/investor event will also be held from the Congress on September 24th, at 6:30 a.m. ET to discuss data presented at ECCO-ESMO. A webcast of the event can be found on Amgen's Web site at [www.amgen.com](http://www.amgen.com), under Investors. The audio webcast will be archived and available for replay for at least 72 hours.

#### About Denosumab

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). With more than 19,000 patients in trials across indications worldwide, 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 induced bone disease. Over 11,000 patients have been enrolled in the denosumab oncology clinical trials testing the drug for bone loss and destruction associated with cancer treatment-induced bone loss in breast and prostate cancers, for the prevention of skeletal related events due to the spread of cancer to the bone in multiple myeloma and multiple solid tumors, and for its potential to delay bone metastases in prostate cancer.

In two phase 3 skeletal related events studies reported to date, the incidence of adverse events and serious adverse events was consistent with what has previously been reported for denosumab and Zometa. Osteonecrosis of the jaw (ONJ) was seen infrequently in both treatment groups.

#### *About Vectibix*

Vectibix is the first fully human anti-EGFR approved by the U.S. Food and Drug Administration (FDA) for the treatment of mCRC. Vectibix was approved in the United States 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.

In December 2007, the European Commission granted a conditional marketing authorization for Vectibix as monotherapy for the treatment of patients with EGFR-expressing mCRC with wild-type KRAS genes after failure of standard chemotherapy regimens. Vectibix has been launched in over 20 countries, including Switzerland, Australia and Canada. Applications in the rest of the world are pending.

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. Vectibix has not shown a treatment benefit for patients whose tumors had KRAS mutations in codon 12 or 13.

#### *Important Product Safety Information*

**Dermatologic Toxicity:** Dermatologic toxicities occurred in 89 percent of patients and were severe (NCI-CTC grade 3 and higher) in 12 percent of patients receiving Vectibix monotherapy. Withhold Vectibix for dermatologic toxicities that are grade 3 or higher or are considered intolerable. If toxicity does not improve to lesser than or equal to grade 2 within 1 month, permanently discontinue Vectibix. The clinical manifestations included, but were not limited to, dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. Subsequent to the development of severe dermatologic toxicities, infectious complications, including sepsis, septic death, and abscesses requiring incisions and drainage were reported.

**Infusion Reactions:** Severe infusion reactions occurred in approximately 1 percent of patients. Severe infusion reactions included anaphylactic reactions, bronchospasm, and hypotension. Although not reported with Vectibix, fatal infusion reactions have occurred with other monoclonal antibody products. Stop infusion if a severe infusion reaction occurs. Depending on the severity and/or persistence of the reaction, permanently discontinue Vectibix.

#### *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 [www.amgen.com](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 Sept. 16, 2009 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 health care 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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