



## Amgen Highlights Data to Be Presented at ASCO

May 16, 2008

New Data from Denosumab, Vectibix(R) and Mid-Stage Pipeline Demonstrate Progress of Oncology Portfolio

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--May 15, 2008--Amgen (NASDAQ:AMGN) today announced it will present new data from the Company's oncology portfolio on both approved and investigational cancer therapies at the 2008 American Society of Clinical Oncology (ASCO) Annual Meeting that will be held in Chicago from May 30 to June 3, 2008.

"Denosumab, which targets the RANKL pathway, is an example of Amgen's approach to novel drug discovery and development. The giant cell tumor data being presented at ASCO are from a proof-of-concept study exploring the therapeutic activity of denosumab in tumors where RANKL appears to play a mechanistic role. These data support the scientific view that this pathway may play a key role in bone loss and destruction," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "In addition, based on early results, Amgen initiated a suite of exploratory Phase 2 programs across more than 15 tumor types with eight targeted therapeutics. New data from some of these programs will also be presented."

### SELECTED ABSTRACTS OF INTEREST

Abstracts are available and can be viewed on the ASCO Web site at [www.asco.org](http://www.asco.org). Identified below are selected abstracts of interest on Amgen research. Updated data will be presented at the meeting.

#### Denosumab

Researchers will present data from the denosumab oncology development program. An oral presentation of Phase 2 data will look at the effect of denosumab on giant cell tumor (GCT) of the bone, a rare locally aggressive tumor associated with significant skeletal morbidity. Composed of stromal and osteoclast-like giant cells, these tumors contain the protein, RANK Ligand, a key mediator of osteoclast activity. Data from this study provide proof-of-concept for specifically targeting the RANK Ligand pathway. Results of two Phase 2 studies will also describe the effects of denosumab on markers of bone destruction in patients with bone metastases from prostate, breast and other cancers who are treatment-naive, and in those who were previously-treated with IV bisphosphonates.

- Abstract No. 10500 (May 31, 8:00 - 8:15 a.m.): Denosumab treatment of giant cell tumor of bone: interim analysis of an open-label Phase 2 study.
- Abstract No. 9574 (May 31, 2:00 - 6:00 p.m.): Effects of denosumab on bone resorption in patients with solid tumors and bone metastases: comparison of serum-C telopeptide levels from 2 randomized, active-controlled, Phase 2 trials.
- Abstract No. 3596 (June 1, 2:00 - 6:00 p.m.): Denosumab in patients with bone metastases from prostate, breast, and other cancers and elevated urinary N-telopeptide (uNTx) during intravenous bisphosphonate (IV BP) therapy: final results of a randomized, Phase 2 study.
- Abstract No. 546 (June 2, 2:00 - 6:00 p.m.): Subgroup analysis of a randomized, Phase 3 study of the effect of denosumab in women with nonmetastatic breast cancer receiving aromatase inhibitor (AI) therapy.

#### Vectibix(R) (panitumumab)

Pooled safety data from the Vectibix PRIME (20050203) study, an ongoing Phase 3 study evaluating Vectibix in combination with FOLFOX in the first-line treatment of mCRC, will be highlighted in a poster discussion on June 1, 2008. Later in the meeting, a subset of pooled safety results from another Phase 3 study of Vectibix plus FOLFIRI chemotherapy in the second-line setting will be presented (20050181). Also presented will be data from the PRECEPT trial and Phase 1 data evaluating Vectibix in head and neck cancer.

- Abstract No. 4064 (June 2, 8:00 a.m. - 12:00 p.m.): Phase 3 study (20050181) of panitumumab (pmab) with FOLFIRI vs FOLFIRI alone as 2nd-line treatment (tx) in patients (pts) with metastatic colorectal cancer (mCRC): Pooled safety results.
- Abstract No. 4034 (June 1, 11:00 a.m. - 12:00 p.m.): Phase 3 study (PRIME/20050203) of panitumumab (pmab) with FOLFOX compared to FOLFOX alone in patients (pts) with previously untreated metastatic colorectal cancer (mCRC): Pooled safety data.
- Abstract No. 4127 (June 2, 8:00 a.m. - 12:00 p.m.): Panitumumab (pmab) regimen evaluation in colorectal cancer to estimate primary response to treatment (PRECEPT): effect of KRAS mutation status on second-line treatment (tx) with pmab and FOLFIRI.
- Abstract No. 6007 (June 2, 5:15 - 5:30 p.m.): A Phase I study of panitumumab, chemotherapy and intensity-modulated radiotherapy (IMRT) for head and neck cancer (HNC).

#### Mid-Stage Pipeline

Emerging clinical data will be presented on four investigational therapies for patients with advanced solid tumors: in the growth regulation space, AMG 102, a fully human monoclonal antibody that targets the action of hepatocyte growth factor/scatter factor (HGF/SF); and AMG 479, a fully human monoclonal antibody that binds to insulin-like growth factor-1 receptor (IGF-1R); in angiogenesis, motesanib, a highly selective oral agent that targets vascular endothelial growth factor receptors 1, 2 and 3 (VEGFR1-3); and in apoptosis, rhApo2L/TRAIL, a pro-apoptotic receptor agonist (PARA) acting through death receptors DR4 and DR5, that is being co-developed with Genentech.

AMG 102

-- Abstract No. 3570 (June 1, 2:00 - 6:00 p.m.): AMG 102, an HGF/SF:c-met antagonist, in combination with anti-angiogenesis targeted therapies in adult patients with advanced solid tumors.

-- Abstract No. 2051 (June 1, 2:00 - 6:00 p.m.): Phase 2 study of AMG 102, a fully human neutralizing antibody against hepatocyte growth factor/scatter factor, in patients with recurrent glioblastoma multiforme.

#### AMG 479

-- Abstract No. 3583 (June 1, 2:00 - 6:00 p.m.): A Phase 1B study of AMG 479, a type 1 insulin-like growth factor receptor (IGF1R) antibody, in combination with panitumumab (P) or gemcitabine (G).

-- Abstract No. 4617 (June 2, 8:00 a.m. - 12:00 p.m.): AMG 479 enhances the anti-tumor effects of gemcitabine and erlotinib against pancreatic carcinoma xenograft models.

#### Motesanib

-- Abstract No. 3560 (June 1, 2:00 - 6:00 p.m.): Safety and pharmacokinetics (PK) of motesanib diphosphate in combination with gemcitabine (G) and erlotinib (E) for the treatment of patients (pts) with solid tumors.

#### rhApo2L/TRAIL

-- Abstract No. 3539 (May 31, 8:00 a.m. - 12:00 p.m.): Phase 1b study of recombinant human (rh)Apo2L/TRAIL in combination with paclitaxel, carboplatin, and bevacizumab (PCB) in patients (pts) with advanced non-small cell lung cancer (NSCLC).

-- Abstract No. 2525 (June 2, 2:00 - 6:00 p.m.): Population pharmacokinetic (PPK) analysis of recombinant human Apo2L/TRAIL (rhApo2L/TRAIL) in a Phase 1a Study in advanced cancer and lymphoma.

#### Aranesp(R) (darbepoetin alfa)

-- Abstract No. 517 (June 2, 8:00 a.m.): PREPARE trial: A randomized phase III trial comparing preoperative, dose-dense, dose-intensified chemotherapy with epirubicin, paclitaxel and CMF with a standard dosed epirubicin/cyclophosphamide followed by +/- darbepoetin alfa in primary breast cancer: A pre-planned interim analysis of efficacy at surgery.

Note: This is an independent investigator-sponsored study that is part of the Aranesp Pharmacovigilance program.

#### Webcast Information

Amgen will host a webcast with the investment community on Sunday, June 1, at 7:00 p.m. CT to discuss data presented at ASCO. Open to members of the news media, investors and the general public, the webcast can be found on Amgen's Web site, [www.amgen.com](http://www.amgen.com), under Investors. It will be archived and available for replay for at least 72 hours after the event.

#### About Denosumab

Denosumab is the first fully human monoclonal antibody in late stage clinical development designed to specifically target RANK Ligand, an essential regulator of osteoclasts (the cells that break down bone). Denosumab is being investigated for its potential to inhibit osteoclast activity through a targeted mechanism and is not incorporated into bone matrix. In the oncology setting, denosumab is being investigated in treatment-induced bone loss (in breast cancer and prostate cancer patients) and for its potential to delay bone metastases as well as inhibit and treat bone destruction across various stages of cancer.

#### About Vectibix

Vectibix is indicated as a single agent for the treatment of patients with epidermal growth factor receptor- (EGFr) expressing metastatic colorectal cancer 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.

In the European Union, Vectibix is approved as monotherapy for the treatment of patients with epidermal growth factor receptor (EGFr) expressing mCRC with non-mutated (wild-type) KRAS genes after failure of standard chemotherapy regimens.

#### Important Product Safety Information

Dermatologic toxicities, related to Vectibix blockade of EGF binding and subsequent inhibition of EGFR-mediated signaling pathways, were reported in 89 percent of patients and were severe (NCI-CTC grade 3 and higher) in 12 percent of patients receiving Vectibix monotherapy. The clinical manifestations included, but were not limited to, dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. Severe dermatologic toxicities were complicated by infection including sepsis, septic death, and abscesses requiring incisions and drainage. Withhold or discontinue Vectibix and monitor for inflammatory or infectious sequelae in patients with severe dermatologic toxicities.

Severe infusion reactions occurred with the administration of Vectibix in approximately 1 percent of patients. Severe infusion reactions were identified by reports of anaphylactic reaction, bronchospasm, fever, chills, and hypotension. Although fatal infusion reactions have not been reported with Vectibix, fatalities 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 Aranesp

Aranesp(R) (darbepoetin alfa) was approved by the FDA in September 2001 for the treatment of anemia associated with chronic renal failure (CRF),

for patients on dialysis and patients not on dialysis. In July 2002, the FDA approved weekly dosing of Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with non-myeloid malignancies and in March 2006, the FDA approved every-three-week dosing in these patients.

Aranesp was granted marketing authorization by the European Commission in 2001 for the treatment of anemia associated with CRF, in adults and pediatric subjects 11 years of age or older. In 2002, the European Commission approved Aranesp for the treatment of anemia in adult cancer patients receiving chemotherapy with solid tumors. This patient population was subsequently expanded in 2003 to include treatment of symptomatic anemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. Approval was granted in 2004 for extended dosing intervals of once-every-three-weeks in the treatment of anemia in adult cancer patients with non-myeloid malignancies who are receiving chemotherapy and up to once-per-month Aranesp administration in the treatment of anemia in CKD patients not on dialysis. In 2006, the Aranesp label was updated to allow CKD patients on dialysis to switch from recombinant human erythropoietin (rHuEPO) one to three times a week to Aranesp every two weeks. In 2007, the Aranesp label was updated to allow for treatment of anemia associated with CRF, in all European pediatric patients on dialysis or not on dialysis.

#### Important U.S. Aranesp Safety Information

**WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR and THROMBOEMBOLIC EVENTS, and TUMOR PROGRESSION.**

Renal failure: Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis- stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

#### Cancer:

- ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers when dosed to target a hemoglobin of greater than or equal to 12 g/dL.
  - The risks of shortened survival and tumor progression have not been excluded when ESAs are dosed to target a hemoglobin of less than 12 g/dL.
  - To minimize these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusions.
  - Use only for treatment of anemia due to concomitant myelosuppressive chemotherapy.
  - Discontinue following the completion of a chemotherapy course.
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Aranesp is contraindicated in patients with uncontrolled hypertension.

#### Important EU Aranesp Safety Information

Aranesp is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic and other serious events; regional guidelines should be referred to for target and maximum hemoglobin levels, and dose adjustment rules should be performed in line with regional prescribing information.

The most commonly reported side effects in clinical trials were arthralgia, edema, injection site pain, and thromboembolic event reactions. Prescribers are recommended to consult regional prescribing Aranesp, including side-effects, precautions and contra-indications.

#### 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 May 15, 2008 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 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 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 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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SOURCE: Amgen