Amgen Highlights Data to Be Presented at ASCO

May 15, 2009

New Vectibix(R) (Panitumumab) Combination Chemotherapy Data

New Data Reinforce Importance of Infection Prevention in Chemotherapy Patients

Oncology Pipeline Continues to Advance With New Data in Multiple Tumor Types

THOUSAND OAKS, Calif., May 15 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) today announced it will present new data from the Company's oncology portfolio of approved and investigational cancer products at the 2009 American Society of Clinical Oncology (ASCO) Annual Meeting in Orlando, Fla. from May 29 to June 2, 2009. Data will be presented from several programs, including Vectibix(R) (panitumumab), Neulasta(R) (pegfilgrastim), Aranesp(R) (darbepoetin alfa), denosumab, conatumumab (AMG 655), dulanermin (rhApo2L/TRAIL) and AMG 479.

"Data presented at this year's ASCO continue to support the scientific view that the angiogenesis, apoptosis, growth regulation, bone metabolism and hematopoiesis pathways hold promise for the treatment of cancer or the treatment side effects," said Sean Harper, M.D., chief medical officer and head of Global Development at Amgen. "These results further our understanding of the clinical and biological effects of the key molecules in development targeting these pathways. The clinical benefits and safety profiles of some of these molecules will be further evaluated when results from four Phase 3 oncology studies and five Phase 2 programs across multiple tumor types are unveiled by the end of this year."

Selected Abstracts of Interest

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

Vectibix(R) (panitumumab)

Final efficacy and safety results will be presented from the PRECEPT trial evaluating Vectibix in combination with FOLFIRI. Consistent with evidence from panitumumab monotherapy findings, it appears that metastatic colorectal cancer (mCRC) patients with wild-type KRAS tumors have better outcomes than patients with KRAS mutated tumors when treated with Vectibix in combination with FOLFIRI. This may be due to KRAS having a predictive and/or prognostic effect which is currently being evaluated in ongoing randomized trials.

As detailed in the ASCO April 17, 2009 press release, findings from the STEPP trial, a randomized, Phase 2 trial evaluating preventive therapy for a common, severe skin rash associated with Vectibix treatment, will be included in the June 1st ASCO Press Program.

-- Results from panitumumab (pmab) regimen evaluation in colorectal cancer to estimate primary response to treatment (PRECEPT): Second-line treatment with pmab and FOLFIRI by tumor KRAS status
Lead Author: Cohn A
Abstract No. 4067 (Sunday, May 31, 2009, 8:00am-12:00pm)

-- An analysis of safety in patients (pts) with recurrent and/or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN) receiving chemotherapy (CT) with or without panitumumab (pmab) in a phase 3 clinical trial (SPECTRUM)
Lead Author: Vermorken JB
Abstract No. 6050 (Monday, June 1, 2009, 8:00am-12:00pm)

-- Final STEPP results of prophylactic versus reactive skin toxicity (ST) treatment (tx) for panitumumab (pmab)-related ST in patients (pts) with metastatic colorectal cancer (mCRC)
Lead Author: Mitchell E
Abstract No. CRA4027 (Monday, June 1, 2009, 8:00am-12:00pm)

-- Updated analysis of a phase 2 study (20060314) of panitumumab (pmab) with FOLFIRI as first-line treatment of patients (pts) with metastatic colorectal cancer (mCRC)
Lead Author: Greil R
Abstract No. 4085 (Sunday, May 31, 2009, 8:00am-12:00pm)

Neulasta(R) (pegfilgrastim)

Neutropenia is a common and potentially dangerous side effect of myelosuppressive chemotherapy leading to a heightened risk of infection, sometimes life-threatening, among people with cancer. New data evaluate the risk of mortality in cancer patients experiencing febrile neutropenia (neutropenia with fever) based on clinical practice. Another study compares the effectiveness of prophylactic versus delayed use of granulocyte colony-stimulating factors (G-CSFs), including NEUPOGEN(R) (filgrastim) and Neulasta, on neutropenia-related hospitalizations based on clinical practice.

-- Evaluating risk of hospitalization with G-CSF use in real-world oncology practice
Lead Author: Tan H
Abstract No. 6626 (Saturday, May 30, 2009, 2:00pm-6:00pm)

-- Risk of mortality in patients with cancer experiencing febrile neutropenia
Lead Author: Barron R
Abstract No. 9561 (Monday, June 1, 2009, 8:00am-12:00pm)

-- Pegfilgrastim in colorectal cancer (CRC) patients (pts) receiving every-two-week (Q2W) chemotherapy (CT): Long-term results from a phase 2 study
Lead Author: Hecht JR
Abstract No. 4072 (Sunday, May 31, 2009, 8:00am-12:00pm)

Aranesp(R) (darbepoetin alfa)

Final data from the DAHANCA-10 Aranesp pharmacovigilance trial in head and neck cancer patients will be presented.

-- Randomized study of darbepoetin alfa as modifier of radiotherapy in patients with primary squamous cell carcinoma of the head and neck (HNSCC): Final outcome of the DAHANCA-10 trial
Lead Author: Overgaard J
Abstract No. 6007 (Saturday, May 30, 2009, 4:15pm-4:30pm)

Denosumab

Researchers will present data from the denosumab oncology development program, including an oral presentation of final Phase 2 data looking at the effect of denosumab on the treatment of 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.

-- Denosumab treatment of giant cell tumor of bone: results of an open label phase 2 study
Lead author: Thomas D
Abstract No. 10510 (Monday, June 1, 2009, 5:15pm-5:30pm)

Apoptosis

As part of Amgen's mechanistic approach to targeted cancer therapies, the Company's apoptosis program is focused on the development of highly selective therapies to induce cancer cell death. In cancer, the dysregulation of apoptosis is critical in the development and survival of tumors. The Company's apoptosis program includes conatumumab (AMG 655), a molecule designed to target death receptor 5 (DR5) to induce apoptosis selectively in cancer cells, and dulanermin (rhApo2L/TRAIL), a recombinant human protein that targets death receptors 4 and 5 (DR4 and DR5) and induces apoptosis in preclinical models. Amgen is developing dulanermin in collaboration with Genentech. These molecules are being studied for their potential as anticancer therapies in a variety of tumors.

-- A phase 1b study to evaluate the safety and efficacy of AMG 655 in combination with gemcitabine (G) in patients with metastatic pancreatic cancer (PC)
Lead Author: Kindler HL
Abstract No. 4501 (Saturday, May 30, 2009, 8:30am-8:45am)

-- Safety and efficacy of AMG 655 plus modified FOLFOX6 (mFOLFOX6) and bevacizumab (B) for the first-line treatment of patients (pts) with metastatic colorectal cancer (mCRC)
Lead Author: Saltz L
Abstract No. 4079 (Sunday, May 31, 2009, 8:00am-12:00pm)

-- A phase 1b/2 trial of AMG 655 and panitumumab (pmab) for the treatment (tx) of metastatic colorectal cancer (mCRC): Safety results
Lead Author: Rougier P
Abstract No. 4130 (Sunday, May 31, 2009, 8:00am-12:00pm)

-- Phase 1b study of recombinant human Apo2L/TRAIL plus irinotecan and cetuximab or FOLFIRI in metastatic colorectal cancer (mCRC) patients (pts): Preliminary results
Lead Author: Yee L
Abstract No. 4129 (Sunday, May 31, 2009, 8:00am-12:00pm)

Growth Regulation

Amgen's growth regulation program is focused on targeting cellular pathways that regulate cell pre-production, survival, migration and invasion, which cancer cells often escape. Amgen is targeting the IGF-1R pathway, among others, to develop novel approaches that may lead to the development of anticancer therapies.

-- Analysis of biomarkers during early phase clinical development of AMG 479, an investigational fully human monoclonal antibody antagonist of type 1 insulin-like growth factor receptor (IGF-1R)
Lead Author: McCaffery I
Abstract No. 3545 (Saturday, May 30, 2009, 8:00am-12:00pm)

About Vectibix

Vectibix is indicated as a single agent for the treatment of patients with epidermal growth factor receptor (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 demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

Vectibix 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 less 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 Neulasta

Neulasta was approved by the U.S. Food and Drug Administration (FDA) in 2002 to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Similar indications for Neulasta were approved in Europe and Australia the same year.

Neulasta Important Product Safety Information

Ruptured spleen (including fatal cases) and a serious lung problem called acute respiratory distress syndrome have been reported. Call your doctor or seek emergency care right away if you have abdominal or shoulder tip pain, shortness of breath, trouble breathing, or a fast rate of breathing. In rare cases, serious allergic reactions can occur, causing shortness of breath, wheezing, dizziness, swelling around the mouth or eyes, fast pulse, sweating, and hives. Sometimes these symptoms could come back within days after stopping treatment for the allergic reaction. If you start to have any of these symptoms, call your doctor or seek emergency care right away. Sickle cell crises have also been reported.

In a clinical study, mild to moderate bone pain occurred in 31 percent of the patients taking Neulasta and in 26 percent of the patients taking a placebo injection. In most cases, bone pain was controlled with a non-narcotic pain reliever, such as acetaminophen. Other common side effects reported by patients in the study taking either Neulasta or placebo were consistent with the underlying cancer diagnosis and its treatment with chemotherapy, with the exception of bone pain.

About Aranesp

Aranesp was approved by the U.S. Food and Drug Administration (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 nonmyeloid malignancies and in March 2006, the FDA approved every-three-week dosing in these patients.

Aranesp Important Product Safety Information

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

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 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.
-- 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.

Aranesp is contraindicated in patients with uncontrolled hypertension.

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). Amgen is studying denosumab in numerous tumor types across the spectrum of cancer induced bone disease. Over 11,000 patients are currently enrolled in denosumab oncology clinical trials testing the drug for bone loss 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.

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.

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, 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 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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