# Interim Safety Data Presented on Vectibix(TM) (Panitumumab) in Combination with Standard Chemotherapy

January 27, 2008

**Emerging Data From Two Phase 3 Trials Exploring Vectibix in Earlier Lines of Colorectal Cancer Treatment**

**ABSTRACT NUMBERS: 335, 443, 462**

ORLANDO, Fla.--(BUSINESS WIRE)--Jan. 27, 2008--Amgen (NASDAQ: AMGN) today announced interim pooled, blinded safety data from two Phase 3 trials examining Vectibix(TM) (panitumumab) in combination with chemotherapy in first- and second-lines of metastatic colorectal cancer (mCRC) treatment. The respective independent Data Monitoring Committee's reviews of the pooled, or combined, safety data from both arms of these randomized, multi-center trials endorsed the continuation of these studies per protocol. These interim data were presented today at the 2008 Gastrointestinal Cancers Symposium (ASCO GI) in Orlando, Fla.

Vectibix was approved as a monotherapy in the United States (U.S.) in September 2006 for the treatment of patients with epidermal growth factor receptor- (EGFr) expressing mCRC after disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

"We continue to make progress in elucidating the potential utility of Vectibix in the treatment of colorectal cancer," said David Chang, M.D., vice president for oncology clinical development at Amgen. "These Phase 3 studies will provide important information about the efficacy of Vectibix when used in combination with conventional chemotherapy regimens."

PRIME (203) Study

The "PRIME" (Panitumumab Randomized trial In combination with chemotherapy for Metastatic colorectal cancer to determine Efficacy) or "203" trial is a global Phase 3 study investigating Vectibix in combination with FOLFOX chemotherapy as a first-line treatment for patients with mCRC. Patients enrolled in the study were randomized to receive either 6.0 mg/kg of Vectibix and FOLFOX4 once every two weeks (Q2W) or FOLFOX4 alone Q2W. The primary endpoint is progression-free survival and other endpoints include overall survival, objective response rate, time to progression, duration of response and safety.

A pooled interim safety review of 601 patients (302 Vectibix plus FOLFOX; 299 FOLFOX only) of which 99 percent received at least one cycle of therapy showed the following grade 3/4 adverse events: neutropenia (25 percent), diarrhea (10 percent), fatigue (four percent), nausea and pulmonary embolism (three percent, respectively), febrile neutropenia, hypomagnesemia, dehydration and deep vein thrombosis (two percent, respectively). Fifty-four percent of the pooled patient population had a skin reaction with 11 percent of patients having a grade three and less than one percent experiencing a grade four. PRIME study's target accrual goal of approximately 1,150 patients was reached in January 2008.

181 Study

The "181" trial is a global Phase 3 study investigating Vectibix in combination with FOLFIRI chemotherapy as a second-line treatment for patients with mCRC. Patients enrolled in the study were randomized to receive either 6.0 mg/kg of Vectibix and FOLFIRI Q2W or FOLFIRI Q2W alone. The co-primary endpoints are progression-free survival and overall survival, other endpoints include objective response rate, time to progression, duration of response and safety.

A pooled interim safety review for 701 patients (352 Vectibix plus FOLFIRI; 349 FOLFIRI only) of which 99 percent received at least one cycle of therapy showed the following grade 3/4 adverse events: neutropenia (15 percent), diarrhea (9 percent), fatigue (four percent), febrile neutropenia, nausea, dehydration, pulmonary embolism (two percent, respectively), hypomagnesemia and deep vein thrombosis (one percent, respectively) and infection (less than one percent). Sixty-one percent of the pooled patient population had a skin reaction with 12 percent experiencing a grade three and less than one percent experiencing a grade four. Target accrual for this study is approximately 1,100 patients and enrollment is anticipated to be complete by Q1 2008.

In both arms of each trial KRAS mutational status in patients' tumors will be studied as a biomarker for Vectibix activity. Recent data indicate that KRAS gene status may predict efficacy and could potentially serve as a patient selection biomarker for Vectibix monotherapy.

STEPP Study

Also presented at ASCO GI were data from "STEPP" (Skin Toxicity Evaluation Protocol with Panitumumab), the first prospective study that examined differences between pre-emptive and reactive skin treatment for skin toxicities. Patients enrolled in the study either received second-line FOLFIRI-based chemotherapy plus 6.0 mg/kg of Vectibix Q2W (n=32) or irinotecan-based chemotherapy plus 9.0 mg/kg Vectibix (n=26) every three weeks (Q3W) and were randomized to pre-emptive or reactive skin treatment. Pre-emptive skin treatment included the administration of skin moisturizer, sunscreen, topical steroid, and doxycycline.

An interim analysis of 58 patients that completed 14 weeks of Vectibix treatment showed the following adverse events: 72 percent of patients had a grade three or greater adverse event in the Vectibix/FOLFIRI Q2W arm with the most notable events being neutropenia (19 percent), diarrhea and dermatitis acneiform (16 percent) and dehydration (13 percent). In the Vectibix/Irinotecan Q3W arm 50 percent of patients experienced a grade three or greater adverse event with hypokalemia (15 percent) being the most significant.

In this interim analysis the investigator assessed best overall response (complete response plus partial response) in the Vectibix plus FOLFIRI Q2W arm was 31 percent.

About Vectibix

Vectibix is approved 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, 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 December 2007, the European Medicines Agency (EMEA) granted a conditional marketing authorization for Vectibix as monotherapy for the treatment of patients with EGFr-expressing mCRC with non-mutated (wild-type) KRAS genes after failure of standard chemotherapy regimens. Regulatory applications in the rest of the world are still pending.

Important Product Safety Information

Dermatologic toxicities, related to Vectibix blockade of EGF binding and subsequent inhibition of EGF receptor-mediated signaling pathways, included but were not limited to dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. Dermatologic toxicities were reported in 89 percent of patients treated with Vectibix and were severe in 12 percent of patients. Severe dermatologic toxicities were complicated by infection, including sepsis, septic death, and abscesses requiring incisions and drainage. Vectibix may need to be withheld or discontinued for severe dermatologic toxicities.

Severe infusion reactions occurred with Vectibix in approximately 1 percent of patients. Severe infusion reactions were identified as anaphylactic reactions, bronchospasm, fever, chills, and hypotension. Although fatal infusion reactions have not been reported with Vectibix, they have occurred with other monoclonal antibody products. Severe infusion reactions require stopping the infusion and possibly permanently discontinuing Vectibix, depending on the severity and/or persistence of the reaction.

About Amgen

Amgen discovers, develops 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 Jan. 27, 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 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.

CONTACT: Amgen, Thousand Oaks
Christine Regan (Media, U.S.), 805-447-5476
Arvind Sood (Investors), 805-447-1060
SOURCE: Amgen