

# New Data Show Preemptive Treatment May Significantly Reduce Skin Toxicities in Patients Receiving Vectibix(R) (Panitumumab)

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Study Adds to Body of Evidence on KRAS Mutational Status As a Predictive Biomarker of Vectibix Response

BARCELONA, Spain--(BUSINESS WIRE)--June 26, 2008--Amgen (NASDAQ: AMGN) today announced updated results from the STEPP (Skin Toxicity Evaluation Protocol with Panitumumab) trial, the first prospective study to examine differences between preemptive and reactive skin treatment for skin toxicities in metastatic colorectal cancer (mCRC) patients receiving epidermal growth factor receptor (EGFr) therapy. The analysis found that preemptive treatment reduced the incidence rate of grade 2 and greater skin toxicities by over 50 percent without additional side effects when compared to reactive skin treatment. The incidence of grade 3 or greater skin toxicities were 62 percent and 29 percent in the reactive and preemptive treatment groups respectively (odds ratio (95 percent CI): 0.3 (0.1. 0.6)). These data were presented at the 10th World Congress on Gastrointestinal Cancer in Barcelona, Spain.

In this patient population, the time to severe skin toxicity was significantly delayed by preemptive skin treatment; at 6 weeks the event- (grade 2 or greater skin toxicity) free probabilities were 70 percent and 38 percent for the preemptive and reactive arms respectively (difference: 32.2 percent (95 percent CI: 12.8, 51.7) in favor of the preemptive arm). Time-to-first-occurrence of any specific grade 2 or higher skin toxicity was also significantly delayed in the preemptive arm. The estimated median time to the first occurrence was 2.7 weeks (95 percent CI: 2.1, 6.3) in the reactive arm and it was not reached in the preemptive arm.

Skin toxicity, or rash, is one of the most common side effects of EGFr inhibitors like Vectibix(R) (panitumumab). The secondary endpoints were safety and efficacy and the analysis included data from 95 patients who had the opportunity to complete 14 weeks on study. Consistent with previous results, analyses by KRAS favored the wild-type group for all efficacy endpoints.

Since skin rash is the most common side effect of EGFr therapy, the results of the STEPP trial showing that skin rash may be controlled by a relatively simple preemptive treatment, represent a significant advancement, said David Chang, M.D., vice president for oncology clinical development at Amgen. In addition, these data add to the growing body of evidence supporting the utility of Vectibix in combination with chemotherapy for patients with wild-type KRAS tumors.

#### About STEPP

Patients enrolled in STEPP received, at the discretion of the investigator, either second-line FOLFIRI-based chemotherapy plus 6.0 mg/kg of Vectibix every two weeks (Q2W) or irinotecan-based chemotherapy plus 9.0 mg/kg Vectibix every three weeks (Q3W) and were randomized to preemptive or reactive skin treatment. Preemptive skin treatment included the administration of skin moisturizer, sunscreen, topical steroid and oral doxycycline. The primary endpoint was the incidence of grade two or greater skin toxicities during the six-week skin treatment period. Secondary endpoints included safety and efficacy.

The analysis of 95 patients showed the following adverse events (AE): 93 percent of all patients had a Vectibix treatment-related AE; 71 percent of all patients had a grade 3/4 AE. Vectibix dose reductions due to skin toxicities occurred in eight percent of patients. Serious adverse events (SAE) were observed in 38 percent of patients and AEs caused 14 percent of patients to end treatment.

# About Vectibix

Vectibix is U.S. Food and Drug Administration (FDA) 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, mCRC 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. Vectibix is now available in 11 European countries. In the first half of 2008 Vectibix was approved by health authorities in Canada and Australia.

### Important Product Safety Information - EU

Dermatologic related reactions, a pharmacologic effect observed with epidermal growth factor receptor (EGFR) inhibitors, are experienced with nearly all patients (approximately 90 percent) treated with Vectibix. The majority of dermatological reactions are mild to moderate in nature. In clinical studies, subsequent to the development of severe dermatological reactions (including sore mouth), infectious complications including sepsis, in rare cases leading to death, and local abscesses requiring incisions and drainage were reported. Patients who have severe dermatologic reactions or who develop worsening reactions whilst receiving Vectibix should be monitored for the development of inflammatory or infectious sequelae, and appropriate treatment promptly initiated. Severe infusion reactions occurred with Vectibix in approximately one 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.

## Important Product Safety Information - US

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.

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## 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 June 26, 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.

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