



## Vectibix(R) Approved in the European Union for the Treatment of Metastatic Colorectal Cancer

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### Clinically Relevant Biomarker Provides Physicians With the Ability to Predict the Patients Most Likely to Respond to Vectibix Treatment

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Dec. 5, 2007--Amgen (NASDAQ: AMGN) today announced that the European Commission has granted a conditional marketing authorization for Vectibix(R) (panitumumab) as monotherapy for the treatment of patients with epidermal growth factor receptor (EGFr) expressing metastatic colorectal cancer (mCRC) with non-mutated (wild-type) KRAS genes after failure of standard chemotherapy regimens.

Vectibix, a fully human anti-EGFr monoclonal antibody, has been granted a positive Commission decision in the European Union (EU) based upon a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) for marketing authorization in September of this year. This approval is based on a positive benefit / risk assessment in a patient population that currently has few treatment options available to them. As part of the CHMP review, clinical data supporting the utility of KRAS mutation status as a biomarker for clinical outcome were provided.

"It is an exciting time in the oncology arena as we see a shift towards individualized patient care," said Willard Dere, M.D., senior vice president and international chief medical officer at Amgen. "We are pleased that Vectibix has received conditional marketing authorization allowing metastatic colorectal cancer patients to have access to a new targeted treatment option."

These biomarker data were generated from a prospectively defined analysis of the Phase 3, randomized, controlled clinical trial "408" that investigated the treatment effect of KRAS status (non-mutated versus mutated) in Vectibix patients with mCRC. The analysis demonstrated that the effect of Vectibix on progression-free survival (PFS) was confined exclusively to the approximately 60 percent of patients whose tumors harbor normal, non-mutated (wild-type) KRAS. Vectibix had no clinical benefit in patients who had tumors with mutations in KRAS regardless of the endpoint studied. Previously reported pivotal results from "408" demonstrated that Vectibix monotherapy significantly improved PFS and response rates in heavily pre-treated patients with mCRC after failure of standard chemotherapy versus best supportive care.

KRAS plays an important role in cell growth regulation and oncogenesis. Anti-EGFr therapies work by blocking the activation of EGFr, thereby inhibiting downstream events that lead to malignant signaling. However, in patients with tumors harboring a mutated or activated KRAS, the KRAS protein is always turned "on" regardless of whether EGFr has been activated or therapeutically inhibited. Thus, in patients with mutated KRAS, signaling continues despite anti-EGFr therapy. Mutant KRAS is detected in approximately 40 percent of CRC tumors.

"Being able to select which patients are more likely to respond to therapy is an important step forward in the treatment of metastatic colorectal cancer," said Professor Eric Van Cutsem, Digestive Oncology Unit, University Hospital, Leuven, Belgium, a Vectibix investigator. "The ability to predict the patient population more likely to respond to Vectibix could potentially reduce drug exposure in patients who we know will not respond."

#### About Vectibix

Vectibix, the first fully human IgG2 monoclonal antibody (MAb) therapy, targets the EGFr, a protein that plays an important role in cancer cell signaling. With its demonstrated efficacy and convenient Q2W dosing schedule Vectibix provides an important option in the management of mCRC patients. Ongoing Phase 3 trials are exploring the potential of administering Vectibix in combination with chemotherapy in the first- and second-line of mCRC, as well as in the head and neck cancer setting.

In the EU, Vectibix is indicated as monotherapy for the treatment of patients with metastatic colorectal carcinoma expressing EGFr with tumors with non-mutated KRAS and after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

Approved by the Food and Drug Administration (FDA) in September 2006, Vectibix is indicated in the United States (U.S.) as a single agent for the treatment of patients with EGFr-expressing, metastatic colorectal carcinoma with 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.

#### 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 stomatitis), 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.

#### Important Product Safety Information - U.S.

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 90 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 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.

#### 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, effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics has 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 involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended Dec. 31, 2006, and in our periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign), difficulties or delays in manufacturing our products. In addition, sales of our products are affected by 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. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. 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. Further, 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. 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, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers.

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