

Vectibix (panitumumab)

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FDA Approves Amgen Colon Cancer Drug Vectibix

By Deena Beasley and Bill Berkrot

LOS ANGELES/NEW YORK (Reuters) Sept 28 – The U.S. Food and Drug Administration said on Wednesday it had approved Amgen Inc.'s drug Vectibix (panitumumab) for use in colon cancer patients whose tumors have spread despite chemotherapy.

The drug, which works by blocking epidermal growth factor, is expected to compete with Erbitux (cetuximab) from ImClone Systems Inc. It received accelerated approval from the FDA after showing effectiveness in slowing tumor growth and, in some cases, reducing the size of the tumor.

Amgen said Vectibix will be on the market in early to mid-October and will be priced about 20% below Erbitux, or about \$8,000 a month.

An Amgen spokeswoman said the company expects to report in January preliminary results from trial of Vectibix as an initial treatment for colon cancer.

The company also announced a financial assistance program for patients who are uninsured, underinsured, or unable to afford their insurance co-payments.

"This approval adds a treatment option for patients with an advanced stage of a disease that can be life-threatening," Dr. Steven Galson, director of FDA's Center for Drug Evaluation and Research, said in a statement.

A pivotal-stage trial showed that patients treated with Vectibix showed a better-than-expected 46% decrease in the rate of tumor growth versus those who received supportive care.

As part of the approval, Amgen committed to conduct a post-marketing trial to show whether the drug lengthens survival in patients with fewer prior chemotherapies, the FDA said.

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<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01468.html>

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FDA Approves a New Drug for Colorectal Cancer, Vectibix

The Food and Drug Administration (FDA) today approved Vectibix (panitumumab) for the treatment of patients with colorectal cancer that has metastasized (spread to other parts of the body) following standard chemotherapy. Vectibix, a monoclonal antibody that binds to a protein called epidermal growth factor receptor or EGFR on some cancer cells, received an accelerated approval after showing effectiveness in slowing tumor growth and, in s