



HEALTH CANADA APPROVES 'PERSONALIZED MEDICINE' FOR METASTATIC COLORECTAL CANCER

Biomarker technology move us a step closer to getting the right drug to the right patient

Mississauga, Ontario, May 15, 2008 – The first and only treatment of its kind in Canada for metastatic colorectal cancer has received conditional* approval from Health Canada. Vectibix™ (panitumumab) represents an important new option for colorectal cancer patients whose disease has progressed following standard chemotherapy regimens. As monotherapy, Vectibix™ has been shown to significantly reduce the chance that certain patients' metastatic colorectal cancer would continue to grow.¹

Vectibix™ is the first and only treatment for metastatic colorectal cancer to have data in its approved label showing how to predict which patients are most likely not to benefit from treatment. Prior to treatment, patients can be tested to see whether the *KRAS* gene mutation is present. Patients with the mutated *KRAS* gene will not benefit from Vectibix™ therapy therefore unnecessary treatment can be avoided.¹

"Vectibix™ represents a significant therapeutic option for patients with metastatic colorectal cancer. The use of *KRAS* biomarker testing is a means to optimize treatment outcomes as it allows healthcare resources to be directed towards those patients who are most likely to benefit from Vectibix™, while those who are not can be redirected to other treatment options. This advance brings us one step closer to personalized medicine in oncology," said Dr. Thierry Alcindor, assistant professor of Medicine and Oncology, McGill University Health Centre, and co-investigator of one Vectibix clinical trial.

A biotechnology medicine, Vectibix™ is the first fully human EGFr monoclonal antibody for the treatment of colorectal cancer. Vectibix™ was developed to offer an effective targeted therapy with a lower risk of the body reacting adversely to the infusion.¹ It works by recognizing and binding to a protein in the body known as epidermal growth factor receptor (EGFr), which is over-expressed on the surface of some cancer cells. When growth factors (other body proteins) attach to the EGFr, the cell is stimulated to grow and divide. Vectibix™ binds to the EGFr and prevents the highly active cancer cell from receiving the messages it needs for growth and division.¹

Vectibix™ is anticipated to be available to patients in Canada summer 2008.

About *KRAS*

The *KRAS* gene plays an important role in cell growth and the development of tumours. In patients whose tumours have mutated *KRAS*, cancer cells continuously receive messages to grow and divide. Mutant *KRAS* is detected in approximately 40% of colorectal cancer tumours, thus Vectibix™ has the potential to benefit 60% of patients with metastatic colorectal cancer.²

KRAS analysis provides guidance in therapeutic treatment decisions for patients with metastatic colorectal cancer. By knowing a patient's *KRAS* mutation status, healthcare professionals are better able to identify whether a person could benefit from Vectibix™ treatment and individualize cancer therapy for their patients. Amgen is working with health agencies and provincial governments to ensure that this type of testing is made available to patients who may be candidates for Vectibix™.

About colorectal cancer

Colorectal cancer, a disease that affects part of the digestive system, is the second leading cause of death from cancer in Canada. It is estimated that in 2008, 21,500 Canadians will be diagnosed with colorectal cancer and 8,900 will die from it.³ For approximately half of patients, diagnosis is made once the cancer has already spread to other parts of the body (also known as metastasis).⁴

About Amgen Canada

Amgen Canada applies science and innovation to help fight serious illness and dramatically improve people's lives. With Canadian headquarters located in Mississauga's vibrant biomedical cluster, and a research facility in Burnaby, British Columbia, Amgen's Canadian affiliate has been an important contributor to Canada's biotechnology sector since 1991. Amgen Canada serves patients throughout Canada by delivering vital medicines to them. In addition, Amgen contributes to the development of new therapies or new uses for existing medicines in partnership with many of Canada's leading healthcare, academic, research, government and patient organizations. Today, tens of thousands of Canadians use Amgen medicines every year, and thousands more are enrolling in Amgen clinical studies to deliver the next generation of innovation.

Important Product Safety Information

The following warnings and precautions are included in the Vectibix™ product monograph:

Dermatologic Toxicity

Dermatologic toxicities, related to Vectibix™ (panitumumab) blockade of EGF receptor occurred in 91% (721/789) of patients and were severe (NCI-CTC grade 3 and higher) in 12% of patients receiving Vectibix™ monotherapy. The clinical manifestations included dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. Severe dermatologic toxicities were complicated by infection, including sepsis, in rare cases leading to death, and local abscesses requiring incision and drainage. It is recommended that patients wear sunscreen and a hat and limit sun exposure while receiving Vectibix™ as sunlight can exacerbate any skin reactions that may occur.

Infusion Reactions

Severe infusion reactions occurred with the administration of Vectibix™ in approximately 1% of patients. Severe infusion reactions were identified by reports of anaphylactic reaction, bronchospasm, fever, chills, and hypotension. Although not reported with Vectibix™, fatal infusion reactions have occurred with other monoclonal antibody products.

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* This conditional authorization reflects the promising nature of the clinical evidence, which must be verified with further studies. Products approved under Health Canada's NOC/c policy, have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment.

¹ Vectibix Product Monograph

² Amado RG, Wolf M, Peeters M et al. Wild-Type *KRAS* Is Required for Panitumumab Efficacy in Patients With Metastatic Colorectal Cancer *J Clin Oncol* 2008;26:1626-1634.

³ Colorectal Cancer Association of Canada Web site, <http://www.colorectal-cancer.ca/en/just-the-facts/colorectal/>

⁴ US National Cancer Institute Web site, <http://seer.cancer.gov/statfacts/html/colorect.html>