

Basel, 15 June 2000

Roche's novel oral treatment for colorectal cancer approved in New Zealand - effective oral chemotherapy

Roche announced today that Xeloda® (capecitabine), an oral chemotherapy for the treatment of metastatic breast cancer, has received its first approval for metastatic colorectal cancer. The New Zealand Ministry of Health has approved the drug for first-line use in patients with colorectal cancer that has spread to other organs or grown inoperable beyond the colon wall.

"The approval of Xeloda for metastatic colorectal cancer validates the extensive clinical testing we have done in patients around the world," said Dr. Peter Teuber, Xeloda Life Cycle Leader at Roche. "Xeloda has been shown to shrink tumors better than standard therapy, while providing a comparable survival benefit and an improved safety profile. Also, because it is taken as a tablet, Xeloda therapy reduces the need for patients to travel to a clinic or hospital for intravenous treatment."

According to the World Health Organization, in 1990 – the last year that statistics are available – more than 780,000 people were diagnosed with colorectal cancer, and more than 435,000 people died that year from the disease.

The New Zealand approval was based on the results of two large multi-centre phase III clinical trials, which involved a total of 1,200 patients at 120 hospitals and cancer centers worldwide. Xeloda was administered at twice daily 1250 mg/sqm, for two weeks followed by a one-week rest period and repeated in three week cycles.

The results indicate that Xeloda has at least equivalent efficacy to a current standard of care for metastatic colorectal cancer, fluorouracil (5-FU) and leucovorin, known as the Mayo Clinic regimen. The drug showed superior tumor shrinkage to the Mayo regimen and an at least equivalent time to progression and survival benefit.

Xeloda, manufactured by Roche, is the first oral drug that works through a unique enzymatic activation to convert Xeloda to the potent cancer-fighting substance 5-FU actually within the cancer cells themselves. Because the enzyme that activates Xeloda is found at high levels in cancer cells, Xeloda is preferentially activated to 5-FU in tumor tissue. 5-FU itself is a standard therapy for colorectal cancer, but until now could only be administered intravenously. This unique mechanism of action of Xeloda is important in delivering the increased tumor shrinkage and improved safety profile compared to standard 5-FU intravenous therapy.

Xeloda is approved in 34 countries for patients with metastatic breast cancer who have not responded to or are no longer responding to chemotherapy with both Taxol® (paclitaxel) and an anthracycline-containing chemotherapy regimen such as one containing Adriamycin® (doxorubicin). Xeloda is under regulatory review for metastatic colorectal cancer in over 50 countries, including the United States, the European Union, Canada and Switzerland.

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address prevention, diagnosis and treatment of diseases, thus enhancing people's well-being and quality of life.