

Basel, 19 October 2001

Roche Receives Positive Recommendation in Europe for “Smart Tablet” Xeloda in Breast Cancer
Xeloda/Taxotere Combination Extends Survival in Metastatic Breast Cancer Patients

Roche announced today that the European Committee for Proprietary Medicinal Products (CPMP) recommended the approval of Roche’s anti-cancer tablet Xeloda for the treatment of metastatic breast cancer. The CPMP recommended two indications, Xeloda monotherapy after failure of intensive chemotherapy, and combination of Xeloda with Aventis’ Taxotere after failure of anthracycline treatment.

In September this year the U.S. Food and Drug Administration (FDA), after priority review, had approved the Xeloda/Taxotere combination therapy for the treatment of metastatic breast cancer patients for whom prior anthracycline treatment had failed.

The CPMP positive opinion was based on study results demonstrating Xeloda/Taxotere to be the first and only combination chemotherapy to show a significant survival advantage in patients with metastatic breast cancer, compared to a standard treatment, Taxotere monotherapy. Patients treated with Xeloda/Taxotere had a three-month survival advantage (at the median) compared to those treated with Taxotere alone. In addition to superior survival, the Xeloda/Taxotere combination also demonstrated superior tumour shrinkage and prevented tumour growth for longer compared with Taxotere alone.

“This CPMP recommendation means that Xeloda will be available for patients with breast cancer in the European Union early next year”, said William M. Burns, Head of the Pharmaceutical Division and Member of the Roche Executive Committee. “The Xeloda data has created an overwhelming response from the oncology community and we believe Xeloda will play a major role in breast cancer care for many years to come.”

Xeloda in Combination with Taxotere

The “smart tablet” Xeloda (capecitabine) has a unique mechanism of activation. It is activated by an enzyme, found at higher levels in cancer cells than in healthy cells. This leads to more of the cancer-killing agent 5-FU being produced in cancer cells, where it is needed. Taxotere (docetaxel) further increases the levels of this enzyme in cancer cells, potentially leading to even more Xeloda being converted into cancer-killing 5-FU.

“The new Xeloda/Taxotere combination therapy represents major progress for the care of women with metastatic breast cancer,” said Professor Robert Leonard, Director South Wales Cancer Institute, United Kingdom. “The three month survival benefit is so exciting because it is very rare to see any improvement in survival in these patients. Moreover, it is a benefit occurring over and above the benefit obtained from Taxotere alone, which is probably the most active cytotoxic agent we have at the moment. More women with metastatic breast cancer will live longer thanks to the Xeloda/Taxotere combination. This is extraordinary news for these women and their families.”

Xeloda Monotherapy

The CPMP recommended the approval of Xeloda monotherapy for the treatment of patients with metastatic breast cancer after failure of standard treatment options. Upon its approval, Xeloda will be the first option for patients where standard therapies failed. The Xeloda monotherapy approval was based on data from two large multinational clinical trials.

Breast Cancer

Breast cancer is a primary cause of cancer-related deaths in women and the third leading cause of overall mortality. Almost 384,000 patients are newly diagnosed with breast cancer in Europe annually and in excess of 165,000 women will die from the disease this year¹. About 50 percent of breast cancer patients develop metastatic disease after primary treatment and the average survival time for patients after diagnosis of metastatic disease is 18 to 30 months.

Xeloda

Xeloda is registered in more than 50 countries worldwide for the treatment of metastatic breast cancer as monotherapy. This September, the U.S. Food and Drug Administration (FDA) was the first health authority to approve Xeloda/Taxotere for the treatment of patients with metastatic breast cancer for whom prior anthracycline chemotherapy had failed, following priority review.

Roche also received marketing authorisation in the United States and Europe for Xeloda in the treatment of metastatic colorectal cancer earlier this year. Xeloda development in other cancer indications and in combination with other cancer treatments is ongoing.

About Roche

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 needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well-being and quality of life.

Roche is a world leader in oncology. Its franchise includes Xeloda, Herceptin (breast cancer), MabThera (non-Hodgkin's lymphoma), NeoRecormon (anaemia), Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma), Neupogen (neutropenia) and Kytril (chemotherapy and radiotherapy-induced nausea).

¹ World Health Organisation, 2000

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