

Basel, 9 April 2001

Xeloda and Taxotere in combination show superior survival benefit in breast cancer - Roche files for breast cancer indication in Europe

Roche announced today that it has submitted an application to the European authorities (CPMP) for its oral cancer drug, Xeloda, in combination with Taxotere from Aventis. Xeloda/Taxotere is the first cytostatic combination chemotherapy to show significantly superior survival compared to a standard monotherapy in patients with advanced breast cancer.

Superior Survival

The filing is based on a major clinical trial of Xeloda (capecitabine) in combination with Taxotere, compared to Taxotere alone. The study was conducted in Europe, the United States, Canada, Australia, Asia and Latin America and involved women with advanced breast cancer previously treated with standard chemotherapy (anthracycline).

Patients receiving the Xeloda/Taxotere combination had an overall 25 per cent decreased risk of death when compared to women treated with Taxotere alone. In addition, women in the Xeloda/Taxotere group demonstrated superior improvements in both time to progression and tumour response.

"The findings from this study are striking" said Dr. Chris Twelves, medical oncologist with Beatson Oncology Centre, Glasgow, U.K. "We know that substantially greater numbers of women will be alive at 12 months by combining Xeloda with Taxotere. This can only be very exciting and promising news for women and their families."

According to Dr. Robert Leonard, medical oncologist at Western General Hospital, Edinburgh, U.K., and one of the lead European investigators in the combination study, "This study was very rewarding to conduct and we were excited to see the survival curves separate very early on for the Xeloda/Taxotere group indicating that many patients benefited from the combination therapy and therefore lived longer."

Along with the Xeloda/Taxotere application, Roche has also submitted an application for Xeloda monotherapy for metastatic breast cancer in the EU. Xeloda is approved as monotherapy for metastatic breast cancer in more than 53 countries worldwide.

In addition, Xeloda is also indicated for the treatment of metastatic colorectal cancer, the third leading cause of cancer worldwide. In February 2001, Roche received EU marketing authorization for this indication.

About breast cancer

According to the World Health Organization, more than 1.2 million people worldwide have been diagnosed with breast cancer in the last year, and more than 700,000 people will die from the disease. In Europe, 206,000 new cases of breast cancer were diagnosed in 1996, the latest year for which statistics are available.

Roche in oncology

Roche is a world leader in oncology. Its franchise comprises such important products as Xeloda (breast cancer and colorectal cancer), Herceptin (breast cancer), MabThera (Non-Hodgkin's lymphoma), NeoRecormon (anemia in cancer patients), Roferon-A (leukemia, Kaposi's sarcoma, malignant melanoma), Bondronat (tumour-induced hypercalcemia), Furtulon (malignant tumours, only available in Japan) and the anti-emetic drug Kytril (used in chemotherapy induced emesis). These medicines along with a number of diagnostics tests have made Roche one of the industry's most innovative and comprehensive companies in the field of oncology.

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 has approximately 64,000 employees and sells its products in over 170 countries.

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