

Basel, 2 August 1999

Roche receives marketing clearance in first European country for Herceptin®

The Swiss regulatory authorities have granted marketing approval for Herceptin, Roche's novel treatment for metastatic breast cancer. Herceptin is the first oncoreceptor-targeted treatment which increases overall survival of patients. Herceptin will be available to Swiss patients as of today.

Approximately 30% of women with breast cancer overexpress a protein called the HER2 (human epidermal growth factor receptor 2) receptor. This overexpression of HER2 protein is associated with a more aggressive form of breast cancer. Herceptin works by targeting these HER2-overexpressing tumors and blocking the HER2 receptors. This novel mechanism - targeting a root cause of metastatic breast cancer - translates into significant clinical benefits.

Herceptin is indicated for the treatment of those patients with metastatic breast cancer who have tumors that overexpress the protein HER2 and as a single agent for the treatment of those who have received one or more chemotherapy regimens for their metastatic disease. It is also indicated in combination with paclitaxel for the treatment of those who have not received chemotherapy for their metastatic disease.

Herceptin prolongs life

The regulatory approval was based on clinical data from phase II and III studies which demonstrated the drug's efficacy and safety in metastatic breast cancer. In a large, randomized study, the addition of Herceptin to standard chemotherapy resulted in a significant increase in time to disease progression of 65 percent from 4.6 to 7.6 months.

This pivotal trial was presented at this year's American Society of Clinical Oncology Congress and it also demonstrated an increase in overall survival, measured by a reduction in mortality rate of 24 percent when compared to women who received chemotherapy alone, and a shift in median survival time by 25 percent from 20.3 months to 25.4 months.

Herceptin when administered alone in a second large study also showed good efficacy and tolerability and almost none of the commonly observed side-effects associated with chemotherapy such as hair loss, nausea and vomiting.

Genentech, the world's leading biotechnology company in which Roche owns a majority share, has successfully launched Herceptin in the United States in the fall of 1998.

Roche and Genentech continue to work on a joint global development program to explore the clinical efficacy and safety of Herceptin in other solid tumours which overexpress HER2, such as non-small cell lung cancer and colorectal cancer.

Roche has marketing rights for all countries outside the USA. Switzerland is the first country in Europe to approve Herceptin.

On February 4, 1999, Roche filed for marketing authorisation in the European Union. Roche is working closely with regulatory authorities worldwide to make this important new therapy available to patients as soon as possible.

Herceptin complements the existing Roche oncology portfolio of highly innovative compounds, such as Xeloda for the treatment of metastatic breast cancer, MabThera for the treatment of follicular non-Hodgkin's lymphoma and Roferon-A, the first interferon treatment for different forms of cancer.

Headquartered in Basel, Switzerland, Roche is one of the world's leading healthcare groups in the fields of pharmaceuticals, diagnostics, vitamins and fragrances and flavours. Roche's products and services address all stages of individual health maintenance and disease management, including prevention, diagnosis and treatment, thus enhancing people's well being and quality of life.