

Basel, 30 August 2000

Roche Receives EU Approval for Herceptin

Roche announced today that the European Commission has approved Roche's monoclonal antibody Herceptin, for the treatment of HER2-positive metastatic breast cancer. Herceptin is recognized as a breakthrough treatment of breast cancer in patients who were diagnosed HER2-positive. The drug has already been approved in the U.S. and a number of other countries.

Herceptin Prolongs Life

The regulatory approval was based on clinical data from two pivotal trials which demonstrated the drug's efficacy and safety in metastatic breast cancer. In a large, randomised study, the addition of Herceptin to standard chemotherapy resulted in approximately 40% improvement in survival for patients who were strongly HER2-positive. When administered alone Herceptin also showed good tolerability and almost none of the commonly observed side effects associated with chemotherapy.

About Herceptin

Herceptin is the first oncogene-targeted breast cancer treatment with proven survival benefits. It is designed to specifically target the HER2 gene, which is associated with aggressive cancer cell growth. Unlike chemotherapeutic regimens, Herceptin does not destroy normal, healthy cells, which is the primary cause of unwanted side-effects associated with traditional treatments. More importantly the clinical use of Herceptin, has resulted in significant improvement in survival outcomes, time to disease progression and quality of life for patients with HER2-positive metastatic breast cancer.

Appropriate Patient Selection Results in Superior Treatment

Herceptin is designed specifically for HER2 positive patients and, as clinical trials have shown, careful selection of these patients results in improvement in survival, quality of life and a better utilisation of clinical resources. The availability of Herceptin means HER2 testing is an essential part of breast cancer management today. This is a strong example of Roche's Integrated Health Care Solution's concept, as Roche's diagnostic expertise helps doctors select the right patients to treat with Herceptin.

Herceptin Regulatory History

Herceptin was approved by the U.S. Food and Drug Administration as a treatment for metastatic breast cancer in September 1998. Since that time, marketing authorisation has been granted in a number of other countries including Argentina, Brazil, Canada, Israel, and Switzerland. Regulatory filings have been made by Roche for the drug in other countries worldwide. Herceptin was discovered and developed by Genentech, a leading US biotechnology company in which Roche holds a majority stake. In July 1998, Genentech granted Roche exclusive marketing rights for Herceptin outside the USA.

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.

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