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Japan approves breakthrough breast cancer drug Herceptin

Women with advanced breast cancer in Japan will soon be able to receive Herceptin after the approval by health authorities in Tokyo.

Herceptin is already approved for the treatment of metastatic (advanced) breast cancer in over 60 countries around the world. Regulatory approval in Japan was primarily based on data from international pivotal trials.

In one of these trials (recently published in the *New England Journal of Medicine*) international investigators found that Herceptin was shown to extend survival by 24 % in HER2-positive women with advanced breast cancer - compared to traditional chemotherapy alone. In fact, in strongly HER2-positive women, this study also found that Herceptin can extend survival by as much as 45%.

As well as increasing survival, Herceptin improves quality of life, has proven tolerability and almost none of the commonly observed side effects associated with chemotherapy.

In Japan, about 34'000 women are newly diagnosed with breast cancer each year. Approximately 1 in 5 women with advanced breast cancer will be HER2 positive. The key determinant to receiving treatment with Herceptin is to be tested for HER2 status - if found HER2-positive, women are then eligible for the drug. Herceptin works by targeting the overactivity of HER2, a gene associated with aggressive cancer cell growth.

Clinical trials have shown that careful selection of HER2-positive 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 a focused diagnostic helps doctors select the right patients to treat with Herceptin.

Herceptin was approved by the U.S. Food and Drug Administration as a treatment for metastatic breast cancer in September 1998. Since then, marketing authorisation has been granted in a number of other countries including the European Union, 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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