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**European Health Authority (CPMP) Supports Use of Herceptin Therapy in the Treatment of Metastatic Breast Cancer; Approval in Europe Expected Later This Year**

Roche announced today that the European Committee for Proprietary Medicinal Products (CPMP) recommends the approval of Roche's monoclonal antibody Herceptin, for the treatment of HER2-positive metastatic breast tumours.

Herceptin, a treatment designed to target a gene called HER2, which is associated with aggressive cancer cell growth, represents an innovative clinical approach to cancer. Unlike traditional chemotherapeutic regimens, Herceptin does not destroy normal, healthy cells, which is the primary cause of unwanted side-effects associated with currently approved chemotherapy regimens. More importantly, as the CPMP recommendation confirms, the clinical use of Herceptin, in combination with chemotherapy, has resulted in significant improvement in survival outcomes, time to disease progression and quality of life for patients with HER2 metastatic breast cancer (MBC).

"The use of Herceptin has proven to be a major advance in terms of survival, and disease progression, for those breast cancer patients with metastatic disease who are at most risk from this particularly aggressive form of breast cancer," said Dr. Martine Piccart of the Jules Bordet Cancer Institute in Belgium and the European Organisation for the Research and Treatment of Cancer (EORTC).

"In one clinical trial, data showed that the combination of Herceptin and chemotherapy increased overall survival. In another trial, using Herceptin as a single agent in a population of patients heavily pretreated with chemotherapy, one third of patients still benefited from this targeted treatment. The duration of this benefit was quite substantial in comparison to what can be traditionally achieved with further chemotherapy," Dr Piccart said.

"Herceptin offers a new alternative to chemotherapy, as it is not associated with distressing side-effects like hairloss and severe sickness – particularly if it is given alone. This treatment has the potential to be used in a similar way to hormonal therapy, the only other targeted therapy for breast cancer, with all the benefits for improved quality of life that this type of treatment brings," she concluded.

The HER2 gene is a known predictor of a poor prognosis, and patients that are found to be HER2-positive represent the greatest treatment challenge using traditional therapeutic regimens. A proportion of patients with MBC are HER2-positive, meaning that a sizeable number of patients with metastatic breast cancer may need a targeted treatment to greatly improve their treatment outcome. Herceptin is designed specifically for these patients and, as clinical trials have shown, careful selection of HER2+ patients results in superior efficacy from Herceptin treatment, resulting in a significant improvement in survival figures. There are, therefore, a significant number of MBC patients that can greatly benefit from Herceptin. The diagnosis of HER2-positive status is made using immunohistochemistry (IHC). IHC is used to determine the amount of HER2 on the tumour cell surface.

Herceptin was approved by the U.S. Food and Drug Administration as a treatment for MBC in September 1998. Since that time, marketing authorisation has been granted in 11 other countries including Israel, Canada, Switzerland, Argentina and Brazil. 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 58 % 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.