

Basel, 6 July 1998

Roche and Genentech sign Licensing Agreement for Herceptin®

Roche and Genentech Inc. today announced that Roche will have exclusive marketing rights outside of the United States for Herceptin® (trastuzumab), Genentech's new and innovative anti-HER2 monoclonal antibody treatment for metastatic breast cancer.

The agreement provides for Roche to pay a substantial up-front fee, cash milestones tied to product development activities, to contribute equally with Genentech to global development costs and to make royalty payments on product sales.

Herceptin's potential as a novel cancer therapy has been received enthusiastically by oncologists worldwide because it targets the root causes of those metastatic breast cancers that overexpress HER2. Standard treatments, such as chemotherapy, attack a wide variety of rapidly dividing human cells, whether malignant or normal.

Herceptin, which was discovered and developed by Genentech, is the first product engineered to target the underlying genetic defect which produces cancer, in this case the overexpression of HER2. In metastatic breast cancer patients, overexpression of HER2 is seen in 25-30 percent of all patients.

The agreement with Genentech also includes a joint global development program for other solid tumors such as non-small cell lung cancer.

Data from Phase III studies which demonstrated Herceptin's efficacy and safety in metastatic breast cancer, were presented at the American Society of Clinical Oncology (ASCO) in May. In one large, randomized and controlled study, in combination with chemotherapy, Herceptin was shown to produce a 53 percent increase in tumor response and a 65 percent increase in median time to disease progression in comparison to chemotherapy alone. The overall safety profile is similar in both randomized groups apart from an increased risk of cardiac dysfunction observed in women receiving Herceptin and anthracyclines at the same time compared to women receiving anthracyclines alone.

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, vomiting and killing of immune system cells.

Herceptin has been designated as a Fast Track product by the US Food and Drug Administration (FDA) and will receive priority review. The FDA is expected to render a decision by November 1998. Roche will file for approval with other regulatory authorities worldwide in the coming months. 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. Together with Praecis Pharmaceuticals, Roche is developing abarelix, a new hormonal antagonist for the treatment of prostate cancer.

Genentech, Inc. is a leading biotechnology company that discovers, develops, manufactures and markets human pharmaceuticals for significant unmet medical needs. Eleven of the currently marketed biotechnology products stem from Genentech science, six of which Genentech markets directly in the United States. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange and the Pacific Exchange under the symbol GNE.

Roche, headquartered in Basel, Switzerland, is a world leader in research-based healthcare with principal business in pharmaceuticals, diagnostics, vitamins, and fragrances and flavours and orthopaedics. Roche discovers, develops and markets prescription drugs in key therapeutic areas such as diseases of the nervous system, virology, infectious diseases, oncology, cardiovascular diseases, inflammatory and autoimmune diseases, dermatology, metabolic disorders and respiratory diseases.