Investor Update

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Herceptin filed for additional indication of early-stage HER2-positive breast cancer in Japan

Chugai and Roche announced today that Chugai filed an application with the Japanese Ministry of Health, Labour and Welfare for the approval of an additional indication of operable early-stage HER2-positive breast cancer for Herceptin.

It has been reported that about 25 to 30% of patients with breast cancer have HER2-positive breast cancer, which demands special and immediate attention because HER2-positive tumours are fast-growing. Currently, Herceptin is widely used as a standard therapy for HER2-positive metastatic breast cancer. Four large clinical studies have been performed to confirm the efficacy of postoperative adjuvant therapy with Herceptin for early HER2-positive breast cancer. Results from interim analyses of all these studies provide consistent evidence that one-year of treatment with Herceptin (with or following standard chemotherapy) reduces the risk of disease recurrence by up to half.

Japanese medical institutions have participated in one of the global studies, the HERA study. Chugai made today's application based on the interim results of HERA study, together with the analysis of the efficacy and safety data of Japanese patients enrolled in the study.

Herceptin is a humanized monoclonal antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential. It has been approved and sold in more than 90 countries, Herceptin is marketed by Chugai in Japan, by Genentech in the US, and by Roche in the rest of the world. In Japan, it was approved for the indication of "metastatic breast cancer with HER2 overexpression" in April 2001 and was launched in June 2001.

Outside of Japan, the European Medicines Agency and the US Food and Drug Administration approved Herceptin for the indication of early-stage HER2-positive breast cancer in May and November 2006, respectively.

About HERA study

The HERA study, conducted by Roche and Breast International Group (BIG), is one of the largest

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postoperative adjuvant therapy studies ever carried out among breast cancer patients; enrollment to the trial began in December 2001, and nearly 5,100 HER2-positive patients were enrolled at 480 sites in 39 countries across the world. The enrollment of patients has been completed in Japanese medical institutions participating in HERA study.

The HERA study is a randomized controlled trial to evaluate efficacy and safety of Herceptin in women with early-stage HER2-positive breast cancer, following standard adjuvant chemotherapy and radiotherapy (if applicable), before or after operation. Patients were either treated or not treated with Herceptin® every three weeks for 1 year or 2 years.

According to the interim analysis (April 2005), the primary efficacy endpoint was met, showing that in the one-year arm, patients who received Herceptin had a statistically significant improvement in disease-free survival (the length of time after treatment during which no disease is found). Twenty-three month follow-up data showed that patients who received Herceptin in the 12-month arm had statistically significant reductions in the risk of death (hazard ratio = 0.66), as well as the risk of cancer coming back (hazard ratio = 0.64).

The HERA study has an external Independent Data Monitoring Committee (IDMC) that regularly reviews safety data. No safety concerns were raised by the IDMC, and at 23-months of follow-up, the incidence of severe congestive heart failure was very low (0.6% in the Herceptin arm vs. 0% in the observation arm). Patients in this study continue to be followed for any side effects.

The interim analysis compared Herceptin versus observation and did not include a comparison of one-year versus two-year treatment duration. The trial will continue to assess this comparison and data will become available in due time as the study matures.

About breast cancer and Herceptin

Eight to nine percent of women will develop breast cancer during their lifetime, making it one of the most common types of cancer in women. Each year more than one million new cases of breast cancer are diagnosed worldwide, with a death rate of nearly 400,000 people per year.

In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumour cells. This is known as 'HER2-positivity.' High levels of HER2 are present in a particularly aggressive form of the disease which responds poorly to chemotherapy. Research shows that HER2-positivity affects approximately 20-30 percent of women with breast cancer.

Herceptin is a humanised antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential. It has demonstrated efficacy in treating both early and advanced (metastatic) breast cancer. Given on its own as monotherapy as well as in

combination with or following standard chemotherapy, Herceptin has been shown to improve response rates, disease-free survival and overall survival while maintaining quality of life in women with HER2-positive breast cancer.

Herceptin received approval for use in the European Union for advanced (metastatic) HER2-positive breast cancer in 2000 and for early HER2-positive breast cancer in 2006. In the advanced setting, Herceptin is now approved for use as a first-line therapy in combination with paclitaxel where anthracyclines are unsuitable, as first-line therapy in combination with docetaxel, and as a single agent in third-line therapy. In the early setting, Herceptin is approved for use following standard (adjuvant) chemotherapy. Herceptin is marketed in the United States by Genentech, in Japan by Chugai and internationally by Roche.

To date, over 310,000 patients with HER2-positive breast cancer have been treated with Herceptin worldwide.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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