CHUGAI PHARMACEUTICAL CO., LTD.
Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome,
Chuo-ku Tokyo, 103-8324 Japan
TEL:+81-(0)3-3273-0881
FAX:+81-(0)3-3281-6607
E-mail:pr@chugai-pharm.co.jp
URL:http://www.chugai-pharm.co.jp

CHUGAI
Roche Roche Group

Translation

Anti-Cancer Agent Herceptin®
Obtained Approval for a New Indication for
Adjuvant Therapy in Breast Cancer that Overexpresses HER2

February 29, 2008 - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter "Chugai")] announced today that it has obtained approval for a new indication of "adjuvant therapy in breast cancer that overexpresses HER2" for humanized monoclonal antibody, "anti-cancer agent trastuzumab (genetical recombination)" [Product name: "Herceptin® Injection 60 and 150" (hereafter, "Herceptin®")] on February 29, 2008 from the Ministry of Health, Labour and Welfare. Herceptin® was initially launched in the Japanese market as a treatment for "metastatic breast cancer that overexpresses HER2" in June 2001.

This approval was granted based on the results of a large-scale clinical study (HERA) of post-operative adjuvant therapy with Herceptin® conducted in breast cancer patients with HER2 overexpression. The latest data from the HERA study* demonstrated that the risks of recurrence and death decreased by 36% and 34%, respectively, in the group treated with "Herceptin®" for one year as compared with the group not receiving the drug. In terms of safety, no new adverse reactions were particularly noted, but attention is continued to be required for cardiac dysfunction specific to "Herceptin®" treatment.

Many Japanese patients participated in the HERA study and contributed to accumulating the data. The use of "Herceptin®" in post-operative adjuvant therapy has been already recommended in Japanese and overseas guidelines for clinical management of breast cancer. The approval of this additional indication expands the treatment options to include post-operative adjuvant therapy for breast cancer patients with HER2 overexpression, which is a highly malignant form of breast cancer.

Chugai places high importance on oncology as one of its strategic therapeutic domains. Chugai hopes to further contribute to cancer treatment in Japan by offering a new treatment option for medical professionals and patients.

About HERA study

HERA (HERceptin Adjuvant) study is a global clinical trial conducted by Roche (Main Office: Basel, Switzerland) and Breast International Group (BIG), a clinical research group in Europe. It was started in December 2001, and nearly 5,100 HER2-positive breast cancer patients were enrolled at about 480 sites in 39 countries across the world. In Japan, 138 patients were enrolled in the study at 7 sites.

HERA study is a randomized controlled trial to evaluate the efficacy and safety of Herceptin® in women with early-stage HER2-positive breast cancer, following standard adjuvant chemotherapy before or after operation, and radiotherapy if applicable. Patients were either treated or not treated with Herceptin® every three weeks for 1 year or 2 years. In the interim analysis, the groups treated with and not treated with "Herceptin®" were compared, but a comparison between the 1-year and 2-year treatments was not included. The follow-up observation is still ongoing in the HERA study, and data for the comparison between the 1-year and 2-year treatments will become available as the study progresses. The enrollment of patients in the HERA study has been completed.

About Herceptin®

"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 is developed by Genentech, Inc. (Main Office: California, the US) and approved as a standard drug for the treatment of HER2-overexpressing metastatic breast cancer in 110 counties or regions including Japan, the US and Europe (as of January 2008). Herceptin® is marketed by Genentech in the US and by Roche in other countries and regions, except for Japan. The drug has been used in nearly 400,000 patients to this date.

References

*: Smith I, Procter M, Gelber RD, et al. 2-year follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer: a randomized controlled trial. Lancet 369: 29 2007

[References]

* The underlined descriptions are newly added.

Brand name:	Herceptin® injection 60 Herceptin® injection 150
Generic name:	Trastuzumab（genetical recombination）
Indications:	Metastatic breast cancer that overexpresses HER2 Adjuvant therapy in breast cancer that overexpresses HER2
Dosage and administration:	1. Metastatic breast cancer that overexpresses HER2 Usually for adults, an initial dose of 4 mg trastuzumab per kilogram body weight, and subsequent doses of 2 mg/kg, are administered as a single intravenous drip infusion over at least 90 minutes once a week. 2. Adjuvant therapy in breast cancer that overexpresses HER2 Usually for adults, an initial dose of 8 mg trastuzumab per kilogram body weight, and subsequent doses of 6 mg/kg, are administered as a single intravenous drip infusion over at least 90 minutes once every 3 weeks.
Drug prices:	Herceptin® injection 60, JPY 30,258/vial Herceptin® injection 150, JPY 73,981/vial