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**Translation**

# Anti-Cancer Agent, Herceptin®
# Obtained Approval for Additional Indication of Advanced or Recurrent Gastric Cancer Overexpressing HER2, Not Amenable to Curative Resection

March 10, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, “Chugai”)] announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) on March 10, 2011 for the additional indication of “advanced or recurrent gastric cancer overexpressing HER2, not amenable to curative resection” for the anti-cancer agent trastuzumab (genetical recombination) [brand name: Herceptin® Injection 60 and 150, hereafter, “Herceptin®”]. In Japan, Herceptin® is currently marketed for the indications of “metastatic breast cancer that overexpresses HER2,” and “postoperative adjuvant chemotherapy in breast cancer that overexpresses HER2.”

In March 2010, Chugai filed an application for approval with the MHLW with results from the global Phase III clinical study (ToGA) that included Japan. ToGA was conducted in patients with inoperable locally advanced, recurrent and/or metastatic HER2-positive gastric cancer.
In the ToGA study, the chemotherapy arm combining fluoropyrimidine anti-cancer agent (Xeloda® or intravenous 5-FU) and cisplatin, and the treatment arm adding Herceptin® to this chemotherapy, were compared. The addition of Herceptin® to Xeloda® or intravenous 5-FU and cisplatin regimen significantly improved overall survival. The safety profile was consistent with the previous reports related to Herceptin® or combination chemotherapy, and both arms were well tolerated.

Gastric cancer is prevalent in Asian countries including Japan, South Korea and China as well as in South America. In Japan, gastric cancer is the second highest causal factor among cancer types that led to deaths (second in male, third in female). It is estimated that there were approximately 110,000 new patients in 2010*.

Herceptin® was approved for HER2-positive metastatic gastric cancer in Europe in January 2010 and in the US in October 2010. Since then, it has become one of the standard treatments recommended by guidelines, outside Japan. With this approval in Japan, Herceptin® is now available for patients with HER2-positive advanced or recurrent gastric cancer and HER2-positive breast cancer (advanced or recurrent / postoperative adjuvant chemotherapy) in Japan as well as US and Europe.

Chugai strongly believes that Herceptin® will make a contribution to patients as a treatment for "advanced or recurrent gastric cancer overexpressing HER2, not amenable to curative resection," an indication with high unmet medical needs. Through development of new treatment options, Chugai will continue its effort to contribute to the advancement of cancer therapies.

* A. Oshima, T. Kuroishi, K. Tajima, "Cancer White Paper - Incidence/Death/Prognosis - 2004" (Shinoharashinsha Inc.)

**[Reference]**

The underlined descriptions are newly added or changed.

Product name: Herceptin® Injection 60
Herceptin® Injection 150

Generic name: Trastuzumab (genetical recombination)

Indications: Metastatic breast cancer that overexpresses HER2
Postoperative adjuvant chemotherapy in breast cancer that overexpresses HER2
Advanced or recurrent gastric cancer overexpressing HER2, not amenable to curative resection

Dosage and administration:

Regimen A should be used for metastatic breast cancer overexpressing HER2. Regimen B should be used as post-operative adjuvant therapy for breast cancer overexpressing HER2. Regimen B should be used concomitantly with other anticancer drugs for advanced or recurrent gastric cancer overexpressing HER2, not amenable to curative resection.

Regimen A:

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.

Regimen B:

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 three weeks.

If the first infusion is well tolerated, the subsequent infusions may be shortened to 30 minutes.

Drug price: Herceptin® Injection 60 JPY 23,992
Herceptin® Injection 150 JPY 56,110