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CHUGAI
Roche Group

**Translation**

# Anti-Cancer Agent, Herceptin®
# Obtained Approval for Additional Indication and Dosage and Administration

November 25, 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 November 25, 2011, for the additional indication of "neo-adjuvant chemotherapy in early breast cancer that overexpresses HER2" and additional dosage and administration of "administration every three weeks for metastatic breast cancer that overexpresses HER2," 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," "postoperative adjuvant chemotherapy in breast cancer that overexpresses HER2," and "advanced or recurrent gastric cancer overexpressing HER2, not amenable to curative resection."

As a result of the evaluation by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs*" held on April 18, an "application based on evidence in the public domain" is applicable when filing for this indication. The decision at the meeting of the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on April 28, confirmed that filing through the "application based on evidence in the public domain" was reasonable for these additional indication and dosage and administration. Thereby, Chugai filed an "application based on evidence in the public domain" for the additional indication and dosage and administration on May 9, and obtained approval by the MHLW. As a result of this additional approval, the indication of Herceptin regarding breast cancer will be integrated and become "breast cancer that overexpresses HER2."

Herceptin®, marketed by Chugai in Japan, has been already approved in more than 100 countries for the treatment of "breast cancer that overexpresses HER2" and over 32 countries for the treatment of "gastric cancer that overexpresses HER2," and has been positioned as one of the global standard therapies.

Chugai is committed to contribute to the advancement of cancer therapies, and hopes that the approval of Herceptin® for "neo-adjuvant chemotherapy in early breast cancer that overexpresses HER2" and "every three weeks administration for metastatic breast cancer that overexpresses HER2," will improve quality of life of patients and the convenience of healthcare professionals.

* The “Review Committee on Unapproved Drugs and Indications with High Medical Needs” was established for the purpose of “enhancing development by the pharmaceutical companies of drugs and indications that have been approved for use in western countries but not yet approved in Japan, through activities such as evaluating medical needs and confirming the applicability of “NDA based on evidence in the public domain” and investigating the need for studies that should be additionally conducted.”

**[Reference]**

The underlined descriptions are newly added.

Product name: Herceptin® Injection 60
Herceptin® Injection 150

Generic name: Trastuzumab (genetical recombination)

Indications: Breast cancer that overexpresses HER2
Advanced or recurrent gastric cancer overexpressing HER2, not amenable to curative resection

Dosage and administration:

Regimen A or B should be used for metastatic breast cancer overexpressing HER2. Regimen B should be used as post-operative adjuvant chemotherapy for breast cancer overexpressing HER2. Regimen A or B should be used as preoperative neoadjuvant chemotherapy of 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:

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| Herceptin® Injection 60 | JPY 23,992 (Diluent included) |
| Herceptin® Injection 150 | JPY 56,110 (Diluent included) |
| Herceptin® Injection 60 | JPY 23,885 (Diluent not included) |
| Herceptin® Injection 150 | JPY 56,003 (Diluent not included) |