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CHUGAI
Roche Roche Group

Translation

Anti-Cancer Agent, Herceptin®
Filed for Additional Indication, and Dosage and Administration
By "New Drug Application Based on Evidence in the Public Domain"

May 9, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, "Chugai")] announced today that on May 9, it filed a "new drug application (NDA) based on evidence in the public domain" with the Japanese Ministry of Health, Labour and Welfare, seeking approval for the indication "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 "NDA based on evidence in the public domain" is applicable when filing for this indication. The filing was made based on the decision at the meeting of the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on April 28, which confirmed that filing through the "NDA based on evidence in the public domain" was reasonable for these additional indication and dosage and administration.

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 will make efforts toward an early approval so that Herceptin® may be used as a treatment for "neo- adjuvant chemotherapy in early breast cancer that overexpresses HER2" and "every three weeks administration for metastatic breast cancer that overexpresses HER2," with hopes that it will improve quality of life of patients and the convenience of patients and 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."