

Translation

Anti-Cancer Agent, Herceptin[®] Obtained Approval for Dosage and Administration for Postoperative Adjuvant Chemotherapy in Breast Cancer

June 14, 2013 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) on June 14, 2013, for the additional dosage and administration of "once a week administration for postoperative adjuvant chemotherapy in 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 "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 "14th Review Committee on Unapproved Drugs and Indications with High Medical Needs" held on December 26, 2012, an "application based on evidence in the public domain" is applicable when filing for this dosage and administration. The decision at the meeting of the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on January 31, 2013, confirmed that filing through the "application based on evidence in the public domain" was reasonable for this dosage and administration. Thereby, Chugai filed an "application based on evidence in the public domain" for the additional dosage and administration on February 7, 2013, and obtained approval by the MHLW.

Herceptin[®], marketed by Chugai in Japan, has already been 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. To date, 1.3 million patients have been treated with Herceptin.

Chugai is committed to contribute to the advancement of cancer therapies, and hopes that the approval of Herceptin[®] for "once a week administration for postoperative adjuvant chemotherapy in 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.”

Herceptin[®] is a registered trademark of Genentech, Inc. (USA).