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Filing of Public Knowledge-Based Application for Anti-Cancer Agent “Xeloda®” for Additional Indication of Adjuvant Chemotherapy for Rectal Cancer

TOKYO, March 2, 2016 - Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has filed public knowledge-based applications for the anti-cancer agent, capecitabine (brand name: Xeloda® Tablets 300) (Xeloda) for the additional indication of “adjuvant chemotherapy for rectal cancer” with the Ministry of Health, Labour and Welfare (MHLW).

As a result of the evaluation by the “26th Review Committee on Unapproved Drugs and Indications with High Medical Needs”* held on February 3, 2016, a “public knowledge-based application” 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 February 26, 2016, which confirmed that filing through the “public knowledge-based application” was reasonable for this indication.

Xeloda was developed by Nippon Roche K.K. (currently Chugai) and has been approved in more than 100 countries worldwide. In Japan, Xeloda is marketed by Chugai and it received approval for “inoperable or recurrent breast cancer” in June 2003. Afterward, Xeloda received approval for the indications of “postoperative adjuvant chemotherapy for colon cancer,” “advanced or refractory colorectal cancer, which is not amenable to curative resection” and “gastric cancer.”

Xeloda has been placed for the standard therapy of “adjuvant chemotherapy for rectal cancer" by the clinical guidelines on Europe and America and results of overseas clinical trials. In order Xeloda to be accessible for Japanese patients sooner, Chugai will continue its effort to receive an approval as soon as possible.

* 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 “public knowledge-based application” and investigating the need for studies that should be additionally conducted.”

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