CHUGAI PHARMACEUTICAL CO., LTD.
Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome,
Chuo-ku Tokyo, 103-8324 Japan
TEL：+81-(0) 3-3273-0881
FAX：+81-(0) 3-3281-6607
E-mail:pr@chugai-pharm.co.jp
URL:http://www.chugai-pharm.co.jp

CHUGAI
Roche Roche Group

Translation

Anti-Cancer Agent, Xeloda®
Filed for Advanced or Refractory Gastric Cancer
By “New Drug Application Based on Evidence in the Public Domain”

September 2, 2010 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, “Chugai”)] announced today that it filed on September 1, a “new drug application (NDA) based on evidence in the public domain” with the Japanese Ministry of Health, Labour and Welfare (MHLW), seeking approval for the indication “advanced or refractory gastric cancer in patients who are not candidates for curative surgery” for the anti-cancer agent capecitabine (brand name: Xeloda® Tablet 300, hereafter, “Xeloda®”). In Japan, Xeloda® is currently marketed for the indications of “inoperable or recurrent breast cancer,” “postoperative adjuvant chemotherapy for colon cancer,” and “advanced or refractory colorectal cancer in patients who are not candidates for curative surgery.”

As a result of the “Review Committee on Unapproved Drugs and Indications with High Medical Needs (hereafter, “the Review Committee”)* held on April 27, the MHLW requested that Chugai develop Xeloda® for the indication of “unresectable advanced or recurrent gastric cancer.” Then on August 3, the Review Committee concluded that an “NDA based on evidence in the public domain” is applicable when filing for this indication.

This 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 August 30, which confirmed that filing through the “NDA based on evidence in the public domain” was reasonable for this indication.

Xeloda®, marketed by Chugai in Japan, has been already approved in many European and Asian countries for the indication of “advanced gastric cancer” and has been used as one of the standard therapies.

Chugai will make efforts toward an early approval so that Xeloda® can be provided to patients as a treatment for “advanced or refractory gastric cancer who are not candidates for curative surgery,” based on high unmet medical needs.

* 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.”