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 ロシュ グループ

Translation

Anti-Cancer Agent **Xeloda[®]**
Obtained Approval for a New Indication for
Postoperative Adjuvant Chemotherapy for Colon Cancer and
Overseas Dosage and Administration

December 14, 2007 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter “Chugai”)] announced today that it has obtained approval for a new indication of postoperative adjuvant chemotherapy for colon cancer and the overseas dosage and administration of the oral fluoropyrimidine “capecitabine” (product name: **Xeloda[®]** 300 mg tablet) on December 12, 2007. **Xeloda[®]** was initially launched in the Japanese market as a treatment for inoperable or recurrent breast cancer in June 2003.

Developed by Nippon Roche K.K. (present Chugai), **Xeloda[®]** has obtained first regulatory approvals in the U.S, Switzerland and Canada in 1998 and in EU in 2001. **Xeloda[®]** is currently approved in over 100 countries worldwide and has been used in over 1.5 million patients as a standard treatment for metastatic breast cancer, colorectal cancer and advanced gastric cancer.

Xeloda[®] is a clinically useful oral anticancer drug with an evidence-based efficacy for postoperative adjuvant chemotherapy for colon cancer. Colon cancer patients treated with **Xeloda[®]** for postoperative adjuvant chemotherapy were shown to achieve a disease-free survival and an overall survival that were at least equivalent to those achieved by patients treated with the global standard treatment 5-FU/LV. In addition to postoperative adjuvant chemotherapy for colon cancer, the overseas dosage and administration of **Xeloda[®]** for inoperable or recurrent breast cancer was approved. Now the treatment supported by the evidences from overseas large-scale clinical studies and clinical experience can be offered to Japanese patients. The oral dosage form of **Xeloda[®]** makes it a pharmaco-economic, easy to use drug with which medication and hospital costs can be reduced.

Chugai places high importance on oncology as one of its strategic therapeutic domains. With regulatory approval of the additional indication and the overseas dosage and administration, Chugai is now able to provide Japanese medical professionals and patients with information on risks and benefits of **Xeloda[®]** based on scientific evidence. Chugai hopes to further contribute to cancer treatment in Japan by offering **Xeloda[®]**, a new chemotherapy choice for patients.

[Reference]

*The underlined descriptions are newly added.

Product name: Xeloda® 300 mg tablet

Generic name: capecitabine

Indications: Inoperable or recurrent breast cancer
Postoperative adjuvant chemotherapy for colon cancer

Dosage and administration:

Regimens A or B are available for the treatment of inoperable or recurrent breast cancer. Regimen B should be used for the treatment of postoperative adjuvant treatment for colon cancer.

Regimen A:

XELODA is administered orally in the following doses, according to body surface area, twice daily within 30 minutes after morning and evening meals for 21 consecutive days, followed by a 7-day rest period. The administration is repeated with this taken as one course. The dosage should be adjusted according to the patient's condition.

Body surfacearea	Each dose
<1.31m ²	900 mg
1.31m ² to <1.64m ²	1,200 mg
1.64m ²	1,500 mg

Regimen B:

XELODA is administered orally in the following doses, according to body surface area, twice daily within 30 minutes after morning and evening meals for 14 consecutive days, followed by a 7-day rest period. The administration is repeated with this taken as one course. Dosage should be reduced according to the patient's condition.

<u>Body surfacearea</u>	<u>Each dose</u>
<u><1.33m²</u>	<u>1,500 mg</u>
<u>1.33m² to <1.57m²</u>	<u>1,800 mg</u>
<u>1.57m² to <1.81m²</u>	<u>2,100 mg</u>

<u>1.81m²</u>	<u>2,400 mg</u>
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Drug price: JPY 368.70/Tablet