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Anti-Cancer Agent “Xeloda®,” Obtained Approval for Additional Indication of “Adjuvant Chemotherapy for Rectal Cancer”

TOKYO, August 26, 2016 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained a supplemental approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) on August 26, 2016, for the anti-cancer agent, capecitabine (brand name: Xeloda® Tablets 300) for the indication of “adjuvant chemotherapy for rectal cancer.” In Japan, Xeloda is currently on the market and its approved indications are “inoperable or recurrent breast cancer,” “postoperative adjuvant chemotherapy for colon cancer,” “advanced or refractory colorectal cancer, which is not amenable to curative resection” and “gastric cancer.” With this supplemental approval, the indication of Xeloda has been changed to “colorectal cancer,” covering the above indications for colon and colorectal cancer.

“Xeloda in adjuvant chemotherapy for rectal cancer is regarded as the standard of care in several guidelines,” said Chugai’s Senior Vice President, Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. “In addition to the current approved indications, this supplemental approval enables people with locally advanced rectal cancer to use Xeloda as well. We believe it will encourage patients to receive treatment with hope and positive thoughts.”

The “26th Review Committee on Unapproved Drugs and Indications with High Medical Needs”* held on February 3, 2016, evaluated whether “public knowledge-based application” might be applicable for Xeloda in adjuvant chemotherapy for rectal cancer. On February 26, the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council made a decision that filing through the “public knowledge-based application” was reasonable. Given that decision, Chugai filed for Xeloda through a “public knowledge-based application” on March 2 and obtained this supplemental approval.

Xeloda was developed by Nippon Roche K.K. (currently Chugai) and has been approved in more than 100 countries worldwide. Chugai strongly believes that Xeloda will make a contribution to patients as a treatment option for “colorectal cancer.” Chugai will continue its efforts to contribute to cancer treatment.

* 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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[Drug Information]

Brand name: Xeloda® Tablets 300

Generic name: Capecitabine

Indications: Inoperable or recurrent breast cancer
Colorectal cancer
Gastric cancer

Dosage and administration:

Regimens A or B are available for the treatment of inoperable or recurrent breast cancer. Regimen B should be employed in adjuvant chemotherapy for colorectal cancer, while regimen C should be employed in combination with another anticancer agent for the treatment of advanced or recurrent colorectal cancer which is not amenable to curative resection. Regimen D should be employed in adjuvant chemotherapy for rectal cancer in combination with radiation therapy. Regimen C should be employed in combination with a platinum agent for the treatment of gastric 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.

Body surface area	Each dose
$<1.31m^2$	900 mg
≥ 1.31 to $<1.64m^2$	1,200 mg
$\geq 1.64m^2$	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. The dosage should be reduced according to the patient's condition.

Body surface area	Each dose
$<1.33m^2$	1,500 mg
≥ 1.33 to $<1.57m^2$	1,800 mg
≥ 1.57 to $<1.81m^2$	2,100 mg
$\geq 1.81m^2$	2,400 mg

Regimen C:
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. The dosage should be reduced according to the patient's condition.

Body surface area	Each dose
<1.36m^2	1,200 mg
≥ 1.36 to < 1.66m^2	1,500 mg
≥ 1.66 to <1.96m^2	1,800 mg
≥ 1.96m^2	2,100 mg

Regimen D:
XELODA is administered orally in the following doses, ac-cording to body surface area, twice daily within 30 minutes after morning and evening meals for 5 consecutive days, followed by a 2-day rest period. This is repeated. The dosage should be reduced according to the patient's condition.

Body surface area	Each dose
<1.31m^2	900 mg
≥ 1.31 to <1.64m^2	1,200 mg
≥ 1.64m^2	1,500 mg

Drug price: JPY 360.2/Tablet