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CHUGAI
Roche Roche Group

Translation

Anti-Cancer Agent, Xeloda®
Obtained Approval for Additional Indication of Advanced or Recurrent Gastric Cancer, which is Not Amenable to Curative Resection

February 23, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, "Chugai")] announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) on 23 February for the additional indication of "advanced or recurrent gastric cancer, which is not amenable to curative resection" 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, which is not amenable to curative resection."

The "Review Committee on Unapproved Drugs and Indications with High Medical Needs*" decided to grant Chugai an "NDA based on evidence in the public domain". The approval follows confirmation by the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on August 30, which decided that filing through the "NDA based on evidence in the public domain" was reasonable for this indication.

Gastric cancer is prevalent in Asian countries including Japan, South Korea and China as well as in South America. In Japan, gastric cancer is the second highest causal factor among cancer types that led to deaths (second in male, third in female). It is estimated that there were approximately 110,000 new patients in 2010**.

Xeloda®, marketed by Chugai in Japan, has been already approved for the indication of "advanced gastric cancer" in more than 100 countries including many European and Asian countries and has been widely used as one of the standard therapies.

Chugai strongly believes that Xeloda® will make a contribution to patients as a treatment for "advanced or recurrent gastric cancer, which is not amenable to curative resection," an indication with high unmet medical needs. Through development of new treatment options, Chugai will continue its effort to improve on current cancer therapies.

* 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."

** A. Oshima, T. Kuroishi, K. Tajima, "Cancer White Paper - Incidence/Death/Prognosis - 2004" (Shinoharashinsha Inc.)

[Reference]

* The underlined descriptions are newly added and changed.

Product name: Xeloda® 300 mg tablet

Generic name: capecitabine

Indications: Inoperable or recurrent breast cancer
Postoperative adjuvant chemotherapy for colon cancer
Advanced or recurrent colorectal cancer, which is not amenable to curative resection
Advanced or recurrent gastric cancer, which is not amenable to curative resection

Dosage and administration:

Regimens A or B are available for the treatment of inoperable or recurrent breast cancer. Regimen B should be employed for the postoperative adjuvant chemotherapy for colon 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 C should be employed in combination with a platinum agent for the treatment of advanced or recurrent gastric cancer, not amenable to curative resection.

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.

Body surfacearea	Each dose
<1.33m^2	1,500 mg
1.33m^2 to <1.57m^2	1,800 mg
1.57m^2 to <1.81m^2	2,100 mg
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. Dosage should be reduced according to the patient's condition.

Body surfacearea	Each dose
$<1.36m^2$	1,200 mg
$1.36m^2$ to $< 1.66m^2$	1,500 mg
$1.66m^2$ to $<1.96m^2$	1,800 mg
$1.96m^2$	2,100 mg

Drug price: JPY 350.5/Tablet