

Translation

Combination Therapy of Anti-Cancer Agents, Xeloda[®], Elplat[®] and Avastin[®], and Monotherapy of Xeloda[®] filed for Advanced or Recurrent Colorectal Cancer

February 29, 2008 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter "Chugai")] announced today that it filed an application with the Japanese Ministry of Health, Labour and Welfare in February 22, 2008, seeking additional approval of combination therapy with capecitabine, an oral fluoropyrimidine (5-FU) anti-cancer agent (brand name: Xeloda[®] Tablet 300 mg, hereafter "Xeloda[®]"), and oxaliplatin (brand name: Elplat[®] for Injection 100 mg, hereafter "Elplat[®]"), plus bevacizumab, a humanized anti-VEGF (Vascular Endothelial Growth Factor) monoclonal antibody (brand name: Avastin[®] for Intravenous Infusion 100 mg/4 mL or 400 mg/16 mL, hereafter "Avastin[®]"), as well as monotherapy of Xeloda[®], for the treatment of advanced or recurrent colorectal cancer.

In Japan, Avastin[®] is recommended to be used in combination with intravenous 5-FU based chemotherapy, and Elplat[®] is recommended to be used in combination with levofolinate and intravenous 5-FU (FOLFOX). Two overseas large-scale clinical studies (NO16966 and NO16967) conducted in patients with metastatic colorectal cancer have demonstrated that XELOX (combination of oral 5-FU anti-cancer agent Xeloda[®] and Elplat[®]) is as effective as FOLFOX in terms of progression-free survival. Tolerance was similar between the two regimens.

In the NO16966 study, it was also confirmed that the addition of Avastin[®] to the XELOX regimen significantly improves progression-free survival compared to XELOX alone. In addition, the interim analysis of Japanese phase I/II clinical studies, conducted in collaboration with Yakult Honsha Co., Ltd. (Main Office: Minato-ku, Tokyo. President: Sumiya Hori), evaluating the addition of Avastin[®] to XELOX regimen in advanced or metastatic colorectal patients who received no prior chemotherapy, demonstrated efficacy and tolerance in Japanese patients that are no different from overseas data.

As for Xeloda[®] monotherapy, in overseas large-scale clinical studies (SO14695 and SO14796), Xeloda[®] achieved superior response rates to those achieved by patients treated with 5-FU/LV regimen (Mayo regimen). In addition, the efficacy and safety in Japanese patients have been confirmed by the Japanese phase II clinical study.

Colorectal cancer is one of the most common cancers in Japan, with an estimated 115,000 new patients in 2005*.

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

[For reference]

About Xeloda®

Xeloda® was initially launched in the Japanese market as a treatment for inoperable or recurrent breast cancer in June 2003 by Chugai, and obtained additional approval for the overseas dosage and administration in breast cancer and a new indication of postoperative adjuvant chemotherapy for colon cancer on December 12, 2007.

About Avastin®

Avastin® was approved as a treatment for metastatic colorectal cancer in the US in February 2004 and is positioned as a standard treatment in the guidelines. In Japan, it was launched in June 2007 as a treatment for patients with advanced or recurrent colorectal cancer who are not candidates for a curative operation.

About Elplat®

Elplat® is positioned as a standard treatment for advanced or recurrent colorectal cancer. In Japan, it was approved in March 2005 and launched in April by Yakult Honsha Co. Ltd. as a treatment for patients with advanced or recurrent colorectal cancer who are not candidates for a curative operation.