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

Translation

Anti-Cancer Agent "Xeloda®" Application for Approval of Additional Indication of "Postoperative Adjuvant Chemotherapy for Gastric Cancer"

December 19, 2014 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that it filed an application with the Japanese Ministry of Health, Labour and Welfare (hereafter, MHLW) for the approval of an additional indication of "postoperative adjuvant chemotherapy for gastric cancer," for the anti-cancer agent, capecitabine (brand name: Xeloda® Tablet 300) (hereafter, "Xeloda®"). In Japan, Xeloda® is currently marketed for these indications of "inoperable or recurrent breast cancer," "postoperative adjuvant chemotherapy for colon cancer," "advanced or refractory colorectal cancer, which is not amenable to curative resection" and "advanced or recurrent gastric cancer, which is not amenable to curative resection."

Chugai filed an application for approval with the MHLW based on the results of two studies: One is a Phase III study MO17527/L9570 (The CLASSIC study) conducted in foreign countries. Another is a Japanese Phase II study (MO28223/LOHP-PII-06) that was co-developed by Chugai and Yakult Honsha Co., Ltd. (Main Office: Minato-ku, Tokyo. President COO: Takashige Negishi).

In The CLASSIC study, patients were randomized to receive either combination therapy of Xeloda® and oxaliplatin after curative gastrectomy (combination group) or surgery alone with follow-up (follow-up group). Disease-free survival (DFS) was evaluated as the primary endpoint.

As a result, the 3-year DFS rate was 74% in the combination group and 59% in the follow-up group, demonstrating statistically significant prolongation of DFS in the combination group (hazard ratio: 0.56, 95% confidence interval: 0.44 to 0.72, $P<0.0001$). Also, for overall survival, a secondary endpoint, 5-year survival was 78% in the combination group and 69% in the follow-up group, showing significant prolongation in the combination group (hazard ratio: 0.66, 95% confidence interval: 0.51 to 0.85, $P=0.0015$). The safety profile shown in the combination group was the same as those which have been reported for the two drugs.

The Japanese Phase II study investigated dose intensity (DI: cumulative dose of each drug actually administered / cumulative dose when 8 cycles were completed without treatment interruption or dose reduction) of Xeloda® and oxaliplatin combination therapy as the primary endpoint. The results of the Japanese Phase II study will be presented at academic conferences and through other means.

Xeloda® was developed by Nippon Roche K.K. (currently Chugai) and approved in 1998 for the first time in the US, Switzerland and Canada, in 2001 in the EU and has been approved in more than 100 countries worldwide. It has been authorized for the indication of “gastric cancer” in more than 95 countries.

Gastric cancer is prevalent in Asian countries including Japan, South Korea and China as well as in South America. In Japan, the number of patients newly diagnosed with gastric cancer continues to rise each year and is estimated to become, on annual average, approximately 133,900 during 2010-2014*.

Chugai strongly believes that Xeloda® will make a contribution to patients as a treatment option for “postoperative adjuvant chemotherapy for gastric cancer.” In order Xeloda® to be accessible for patients and healthcare professionals sooner, Chugai will continue its effort to receive an approval as soon as possible.

* Tomotaka Sobue, et al. “Cancer White Paper 2012 - For data-based cancer control” (Shinoharashinsha Inc.)

About oxaliplatin

Oxaliplatin is a platinum complex, anti-cancer agent of which the development and distribution rights in Japan were obtained by Yakult Honsha Co., Ltd. in 1997 from Debiopharm International SA (Switzerland). Oxaliplatin was approved in March 2005 for an indication of “advanced or recurrent colorectal cancer, which is not amenable to curative resection” and started to be marketed in April 2005. It was approved for additional indications of “postoperative adjuvant chemotherapy for colon cancer” in 2009 and “pancreatic cancer, which is not amenable to curative resection” in 2013.