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

CHUGAI
Roche Roche Group

Translation

Anti-Cancer Agents, Herceptin® and Xeloda®
Filed for HER2-positive Advanced or Recurrent Gastric Cancer

March 19, 2010 (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, seeking additional approval of combination therapy with trastuzumab (genetical recombination), a humanized monoclonal antibody (brand name: Herceptin® for Intravenous Infusion 60 and 150, hereafter "Herceptin®") and capecitabine, an oral fluoropyrimidine anti-cancer agent (brand name: Xeloda® Tablet 300 mg, hereafter "Xeloda®"), for the treatment of HER2-positive advanced or recurrent gastric cancer.

In the global Phase III clinical study (ToGA) conducted for patients with HER2-positive advanced or recurrent gastric cancer, the chemotherapy arm combined with fluoropyrimidine anti-cancer agent (Xeloda® or intravenous 5-FU) and cisplatin, and the treatment arm adding Herceptin® to this chemotherapy, were compared. The addition of Herceptin® to Xeloda® or intravenous 5-FU and cisplatin regimen significantly improved overall survival. The safety profile was consistent with the previous reports related to Herceptin® or combination chemotherapy, and both arms were well tolerated.

Regarding the indication of Herceptin® for HER2-positive metastatic gastric cancer in other countries, F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland. CEO: Severin Schwan] filed the application to expand market approval with the European Medicines Agency in September, 2009 and obtained approval in January this year.

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 the cancer types that led to deaths (second in male, third in female). It is estimated that here will be approximately 110,000 new patients in 2010*.

Chugai positions Oncology as one of its key therapeutic areas, and will prepare for the approval to offer medical practitioners and patients a new treatment option as soon as possible.

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

[Reference]

About ToGA study

ToGA is a global Phase III clinical study for patients with HER2-positive advanced or recurrent gastric cancer. Approximately 3,800 patients were tested for HER2 and 594 HER2-positive patients were enrolled into the study. In the ToGA study, the patients were randomized to receive one of the following regimens as their first line therapy.

- A fluoropyrimidine (Xeloda® or intravenous 5-FU) and cisplatin every 3 weeks
- A fluoropyrimidine and cisplatin in combination with Herceptin every 3 weeks

The primary endpoint of the ToGA study was to confirm whether the overall survival time can be extended by the Herceptin-containing treatment compared to the chemotherapy alone. Secondary endpoints for the study included progression free survival, overall response rate, duration of response, safety and quality of life.

The median overall survival in the Herceptin®-containing regimen was 13.8 months, demonstrating a statistically significant extension compared to the 11.1 months in the chemotherapy alone [hazard ratio: 0.74 (95% CI: 0.60 - 0.91), p=0.0046]. In addition, the progression free survival which is the secondary endpoint demonstrated a statistically significant extension [hazard ratio: 0.71 (95% CI: 0.59 - 0.85), p=0.0046]. And the overall response rate was also increased with Herceptin® from 34.5 % to 47.3%. The patients exhibiting high levels of HER2 (IHC2+/FISH+ or IHC3+) experienced even greater benefit from the addition of Herceptin® with overall survival as 16 months on average compared to 11.8 months for patients receiving chemotherapy alone. The safety profile was consistent with the previous reports related to Herceptin® or combination chemotherapy, and both arms were well tolerated.