

Translation

Anti-Cancer Agent, Herceptin[®]

Designated for Priority Review by Ministry of Health, Labour and Welfare

June 21, 2010 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter "Chugai")] announced today that the Japanese Ministry of Health, Labour and Welfare (MHLW) designated trastuzumab (genetical recombination), a humanized monoclonal antibody (brand name: Herceptin[®] for Intravenous Infusion 60 and 150, hereafter "Herceptin[®]") as a priority review subject on May 18, following an application filed on March 19, 2010 with the MHLW seeking additional approval for the treatment of HER2-positive advanced or recurrent gastric cancer.

The application for additional approval is based on the result of the global Phase III clinical study (ToGA) conducted with patients with HER2-positive advanced or recurrent gastric cancer. In the ToGA study, a chemotherapy arm treated with fluoropyrimidine anti-cancer agent and cisplatin, and a treatment arm adding Herceptin[®] to this chemotherapy were compared. The combination of Herceptin[®] with chemotherapy showed a statistically significant improvement in overall survival for patients with HER2-positive advanced or recurrent gastric cancer, and both arms were well tolerated.

Outside Japan, F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland. CEO: Severin Schwan] filed an application to expand marketing approval of Herceptin[®] with the European Medicines Agency in September 2009 and obtained approval in January 2010 for the treatment of patients with HER2- positive metastatic adenocarcinoma of the stomach or gastroesophageal junction.

Gastric cancer is one of the most prevalent and fatal cancer type worldwide, and the number of new patients who developed the disease in 2007 was estimated to be one million worldwide. In Japan, gastric cancer is the second highest causal factor among cancer patients leading to death (second in male, third in female). It is estimated that approximately 110,000 new cases of stomach cancer will be diagnosed in Japan in 2010*.

Chugai positions oncology as one of its key therapeutic areas, and will prepare for the early approval to offer patients with HER2-positive advanced or recurrent gastric cancer and medical practitioners a new treatment option.

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