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CHUGAI
Roche Group

Translation

Anti-Cancer Agent "Tarceva®," Application for Approval of Additional Indication of Non-Small Cell Lung Cancer (First Line Therapy)

June 26, 2012 (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 (MHLW) for the approval of an additional indication of non-small cell lung cancer (NSCLC) (first line therapy) for the epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, "Tarceva® Tablet 25mg, 100mg and 150mg" [generic name: erlotinib hydrochloride] (hereafter, Tarceva®).

Chugai filed an application for approval with the MHLW based on the results from an overseas clinical trial (EURTAC trial) and a domestic phase II clinical trial.
The EURTAC trial compared Tarceva® monotherapy to platinum-based standard chemotherapies in patients with EGFR mutation positive NSCLC. The study met its primary endpoint by demonstrating statistically significant improvement in progression-free survival in patients who received Tarceva® monotherapy. The safety profile was consistent with the previous reports related to Tarceva®, and was well tolerated.
Similar results were observed in the OPTIMAL trial conducted in China.

Tarceva® was approved in EGFR mutation positive NSCLC in Europe in August 2011.

The number of patients newly diagnosed as lung cancer in Japan is estimated to exceed 110,000 in 2015[1)]. The occurrence of specific gene mutation in EGFR mutation positive NSCLC patients, observed in the EURTAC study, was approximately 10 percent in the Western patients and approximately 30 percent in Asian patients[2)].

As the top pharmaceutical company in the field of oncology, Chugai will work for the approval to provide patients and medical professionals with new treatment options as soon as possible.

1. A. Oshima, T. Kuroishi, K. Tajima, Cancer White Paper - Incidence / Death / Prognosis - 2004, Shinoharashinsha Inc.
2. Rosell R., et al., NEJM 361; 1-10: 2009

About Tarceva®

Tarceva® is a once-daily, oral treatment for advanced or metastatic NSCLC and pancreatic cancer. It has been shown to potently inhibit EGFR, a protein involved in the growth and development of cancers.

In Japan, Tarceva® received approval for “nonresectable recurrent and advanced non-small cell lung cancer which is aggravated following chemotherapy” in October 2007 and “pancreatic cancer, not amenable to curative resection” in July 2011 (Tarceva® Tablet 150mg is not approved for pancreatic cancer.)