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Translation

Antineoplastic Agent / Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitor, Tarceva®
Application for Approval of Additional Indication of Pancreatic Cancer

September 18, 2009 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President Osamu Nagayama (hereafter, Chugai)] announced today that the company filed an application with the Japanese Ministry of Health, Labour and Welfare for the approval of an additional indication of pancreatic cancer for the antineoplastic agent / epidermal growth factor receptor tyrosine kinase inhibitor, "TARCEVA Tablet 25 mg and 100 mg" [generic name: erlotinib hydrochloride] (hereafter, Tarceva®).

Tarceva® is an agent that inhibits the activation of a protein called epidermal growth factor receptor (EGFR) which plays a key role in the formation and proliferation of cancer. The product has been approved in Japan as a treatment for non-resectable, recurrent/advanced non-small cell lung cancer that has become aggravated after cancer chemotherapy.

A pivotal phase III clinical trial was conducted overseas in patients with advanced pancreatic cancer (PA.3 study). The study met its primary and secondary endpoints by demonstrating statistically significant improvement in overall and progression-free survivals in patients who received Tarceva® in combination with a standard chemotherapy, gemcitabine. Based on these data, the drug has been approved as a first-line treatment for patients with pancreatic cancer outside Japan.

Chugai positions Oncology as one of its key therapeutic areas. Pancreatic cancer is one of the most difficult cancers to treat as there are few treatment options for the disease. More than 23000 people are estimated to be killed by pancreatic cancer every year in Japan. Chugai will work for the approval to offer a new treatment option for this difficult cancer to patients and medical practitioners.

About Tarceva®

Tarceva® is a small-molecule agent that targets and inhibits human EGFR tyrosine kinase, which plays a key role in the formation and proliferation of cancer. Tarceva® received approval for the treatment of advanced or metastatic non-small cancer in the U.S. in November 2004 and in Europe in September 2005. Tarceva® was also approved as a treatment for pancreatic cancer in the U.S. in November 2005 and in Europe in January 2007, contributing to cancer treatment.
In Japan, Tarceva® was launched in December 2007 as a once-daily oral treatment for non-resectable, recurrent/advanced non-small cell lung cancer that has become aggravated after cancer chemotherapy.