

Translation

Anti-Cancer Agent, Tarceva[®] Obtained Approval for Additional Indication of “Pancreatic Cancer Not Amenable to Curative Resection” and Measures for Proper Use

July 1, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, “Chugai”)] announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) on July 1, 2011 for the additional indication of “pancreatic cancer, not amenable to curative resection” for the anti-cancer agent erlotinib hydrochloride [brand name: Tarceva[®] Tablet 25 mg, 100 mg, hereafter, “Tarceva[®]”]. In Japan, Tarceva[®] is currently marketed for the indications of “Nonresectable recurrent and advanced non-small cell lung cancer which is aggravated following chemotherapy.”

In September 2009, Chugai filed an application for approval with the MHLW with results from a domestic phase II study and overseas pivotal phase III studies (PA.3 study) for the treatment of “pancreatic cancer, not amenable to curative resection.” The PA.3 study met its primary and secondary endpoints by demonstrating statistically significant improvement in overall and progression-free survival in patients who received Tarceva[®] in combination with a standard chemotherapy, gemcitabine. Based on the results of PA.3 study, Tarceva[®] was approved for pancreatic cancer in the US in November 2005 and in Europe in January 2007.

The efficacy of combination therapy with Tarceva[®] and gemcitabine for pancreatic cancer is confirmed by Japanese and overseas clinical trials. However, considering the previous reports that 1) the incidence of interstitial lung disease (ILD), a serious adverse reaction, is higher than when it is used to treat non-small cell lung cancer; 2) the incidence of ILD reported in Japan is higher than overseas and; 3) there have been deaths caused by ILD overseas, Chugai is committed to ensure strict safety measures are taken and place top priority on ensuring its proper use in order to secure the safety of patients.

Chugai is convinced that Tarceva[®] can contribute to the treatment of patients with “pancreatic cancer, not amenable to curative resection” who have very limited therapeutic options, by providing a new therapeutic option to meet their unmet medical needs.

Note: Only tablets 25mg and 100mg are approved for pancreatic cancer and not 150mg which is currently marketed for lung cancer.

Overview of the safety measures for Tarceva®

Tarceva® may be prescribed to patients with “pancreatic cancer, not amenable to curative resection” at the hospitals that are designated by the Minister of Health, Labour and Welfare as centers of cancer care, by physicians who belong to the Japan Pancreas Society, the Japan Society of Clinical Oncology or the Japanese Society of Medical Oncology. The physicians are required to take an E-learning course.

Once completing the E-learning course, the physicians who are eligible to prescribe Tarceva® and their medical facilities are asked to conduct specific drug use-result survey (all-case surveillance), register patients before administration, conduct tests before administration and during treatments, give explanation to patients, obtain informed consent from patients and hand out a “Tarceva® Tablet Treatment Check Sheet” at each prescription for pancreatic cancer. Chugai, mainly through its medical representatives, is to collect and provide information on the proper use of Tarceva® while explaining the safety measures using the guideline for proper use.

For patients, the above mentioned “Tarceva® Tablet Treatment Check Sheet,” which indicates the initial symptoms of interstitial lung disease and the emergency contact information for the medical institution, is issued at every prescription, and this sheet should be handed with prescription at pharmacy. If this sheet is not issued, the medical representative will explain to the prescribing physician that prescribing Tarceva® requires careful safety measures.

Chugai will add on its website a new page dedicated to the use of “Tarceva® in pancreatic cancer which features the following information to provide a wide range of latest safety information. For patients and their families, there is another dedicated area.

- (1) Outline of all-case surveillance
- (2) Progress of all-case surveillance (regularly updated)
- (3) Adverse drug reactions in all-case surveillance (regularly updated)

For the first 800 patients who will receive Tarceva® treatment, data will be collected. Results of this surveillance will be reported to the regulatory authorities as well as in future scientific meetings and publications.

Tarceva® is a registered trademark of OSI Pharmaceuticals, LLC (USA).

[Reference]

The underlined descriptions are newly added or changed.

Brand name: Tarceva[®] Tablet 25 mg
Tarceva[®] Tablet 100 mg

Generic name: Erlotinib Hydrochloride

Indications: O Nonresectable recurrent and advanced non-small cell lung cancer
which is aggravated following chemotherapy
O Pancreatic cancer, not amenable to curative resection

Dosage and administration:

1. Nonresectable recurrent and advanced non-small cell lung cancer
which is aggravated following chemotherapy

Usually, for adults, 150 mg of erlotinib should be orally administered once daily at least 1 hour before or 2 hours after a meal. The dosage may be reduced according to the patient's symptoms, if necessary.

2. Pancreatic cancer, not amenable to curative resection

In combination with gemcitabine, usually, for adults, 100 mg of erlotinib should be orally administered once daily at least 1 hour before or 2 hours after a meal. The dosage may be reduced according to the patient's symptoms, if necessary.