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## Translation

### On the Launch and Measures for Proper Use of the Anti-cancer Agent Tarceva<sup>®</sup> Tablet

December 14, 2007 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama] (hereafter, Chugai) announced today that erlotinib hydrochloride, epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor [brand name: Tarceva<sup>®</sup> Tablet 25 mg, 100 mg and 150 mg (hereafter, Tarceva<sup>®</sup>)], which, obtained approval on October 19, 2007 from the Japanese Ministry of Health, Labour and Welfare for the treatment of patients with nonresectable recurrent and advanced non-small cell lung cancer (NSCLC) which is aggravated following chemotherapy, has been listed on National Health Insurance (NHI) drug reimbursement price list and will be launched on December 18.

Tarceva<sup>®</sup> is a small molecule created by OSI Pharmaceuticals, Inc. It is approved as a treatment for non-small cell lung cancer in 83 countries and regions including the U.S. and Europe (as of August, 2007). Tarceva<sup>®</sup> is marketed by Genentech and OSI Pharmaceuticals, Inc. in the U.S. and by Roche in the rest of the world, with its launch in Japan awaited.

The efficacy and tolerability of Tarceva<sup>®</sup> were demonstrated in the clinical trials conducted in Japan and overseas, while a low incidence of serious adverse reactions including interstitial lung diseases was reported. Therefore, its use will be limited to the medical institutions which have the sufficient experience in cancer chemotherapy and the ability to provide the effective emergency treatment to the adverse drug reactions, and which are willing to cooperate in all-case surveillance.

Following launch, Chugai will make every effort to collect and provide information on the proper use of Tarceva<sup>®</sup> through its medical representatives, and Chugai's website will have a page devoted to Tarceva<sup>®</sup> after its launch, where the following information is posted to provide the latest safety information.

- (1) Outline of all-case surveillance
- (2) Registration progress of all-case surveillance
- (3) Adverse drug reactions in all-case surveillance

The launch of Tarceva<sup>®</sup> in Japan provides a new option in the treatment of NSCLC, and securing the safety of patients who receive the drug and promoting its proper use will be the top priorities for Chugai.

**[For reference]**

Brand name: Tarceva<sup>®</sup> Tablet 25 mg  
Tarceva<sup>®</sup> Tablet 100 mg  
Tarceva<sup>®</sup> Tablet 150 mg

Generic name: Erlotinib Hydrochloride

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

**Dosage and administration:**

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.

Date of drug price listing: December 14, 2007

Date of launch: December 18, 2007

Shelf life: 3 years

Drug prices:	Tarceva <sup>®</sup> Tablet 25 mg	JPY 1,954.20 / tablet
	Tarceva <sup>®</sup> Tablet 100 mg	JPY 7,183.90 / tablet
	Tarceva <sup>®</sup> Tablet 150 mg	JPY 10,513.00 / tablet

**Conditions for approval:**

A post-marketing surveillance of all patients who receive Tarceva<sup>®</sup> should be conducted until the data of a certain number of patients are accumulated in order to identify the background of the patients and collect safety and efficacy data and take necessary measures for appropriate use of Tarceva<sup>®</sup>;  
Take necessary safety measures to ensure that Tarceva<sup>®</sup> will be handled by doctors, medical institutions and pharmacists, who have sufficient experience in diagnosis and chemotherapy in lung cancer and who can control risks, especially risk of interstitial lung disease, associated with Tarceva<sup>®</sup>."

**About the Tarceva<sup>®</sup> website:**

Patients and their families should consult "Information for Patients and Medical Consumers" and healthcare professionals should consult "Information for Healthcare Professionals".

About the post marketing surveillance of Tarceva<sup>®</sup>:

For the first 3,000 patients who will receive Tarceva<sup>®</sup> treatment, data will be collected and analyzed to be reported to the authority. This process will take approximately 30 months to complete. After collecting the data of 3,000 cases, a review and decision will be made to determine whether a new surveillance or further safety measures should be considered. Results of this surveillance shall be reported to the public in future scientific meetings, as well as to the regulatory authorities.

About Tarceva<sup>®</sup>:

Tarceva<sup>®</sup> is a small molecule designed to target the epidermal growth factor receptor (EGFR) pathway, one of the factors critical to cell growth in NSCLC and other solid tumors. EGFR is a component of the signaling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva<sup>®</sup> is designed to inhibit the tyrosine kinase activity of the EGFR inside the cell, which may block tumor cell growth.

Tarceva<sup>®</sup> is a registered trademark of OSI Pharmaceuticals, Inc. (USA).