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CHUGAI
Roche Group

Translation

Results of a Phase I/II Clinical Trial of a New Anti-Malignant Agent, AF802, for ALK-Positive Non-Small Cell Lung Cancer were Published Online on "The Lancet Oncology"

May 7, 2013 (Tokyo) – Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that the results of the phase I/II clinical trial of a new anti-malignant agent originated by Chugai, AF802 (Compound Number: CH5424802) which is currently in development by Chugai in Japan, were published on the electronic version of "The Lancet Oncology" on April 30, 2013.
http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(13)70142-6/abstract

The phase I/II clinical trial of AF802 published in this journal was conducted at 13 medical institutions in Japan for ALK-positive non-small cell lung cancer patients with a treatment history of chemotherapy. The clinical trial was conducted in two phases; Phase 1 portion was conducted to determine the recommended dose (24 patients) and phase 2 portion was conducted to evaluate the efficacy and safety of the confirmed recommended dose (46 patients). As a result, the recommended dose was confirmed to be 300 mg twice daily in phase 1. Phase 2 was conducted using the confirmed recommended dose, and as a result, tumor shrinkage was observed in 43 (93.5%) of 46 patients. Also, there were no treatment-related deaths and grade 4 or higher serious adverse reactions assessed according to the Common Terminology Criteria for Adverse Events (CTCAE) defined by the Japan Clinical Oncology Group. The most frequently observed CTCAE grade 3 or higher adverse reactions were neutropenia and increase in creatine phosphokinase (CPK). The incidence of both adverse events was 2 (4.3%) of 46 patients.

The results of this clinical trial have been presented at the 37th annual meeting of European Society of Medical Oncology (held on September 2012) and the 53rd annual meeting of Japan Lung Cancer Society (held on November 2012).

As the top pharmaceutical company in the field of oncology, Chugai will work for the early application for approval to provide AF802 as a new treatment option for patients and medical professionals.

[Reference]

About AF802 (CH5424802)

AF802 is an oral ALK (Anaplastic Lymphoma Kinase) inhibitor created by Chugai Kamakura Research Laboratories and the clinical development is currently ongoing. It has been reported that ALK fusion genes are expressed in two to five percent of the patients with non-small cell lung cancer[1)], and it is considered that the ALK kinase activity constantly increases in the cells with this fusion gene, transforming the cells into cancer cells[2, 3)]. AF802 demonstrates its anti-tumor effect by selectively inhibiting the kinase activity, and inhibiting the proliferation of tumor cells and inducing apoptosis[4)]. The rights to AF802 in other countries including Europe and the US have been licensed to F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland. CEO: Severin Schwan], and the clinical trials of AF802 (Roche Development Code: RG7853) are currently ongoing in the US and Europe.

1) Biomarker committee of The Japan Lung Cancer Society, Guidelines for ALK genetic testing in lung cancer patients
2) Soda et al., Nature. 448: 561-566 (2007)
3) Takeuchi et al., Clin Cancer Res. 15: 3143-3149 (2009)
4) Sakamoto et al., Cancer Cell. 19: 679-690 (2011)

AF802 and Personalized Healthcare (PHC)

AF802 is a drug candidate that matches with the PHC strategy that selects an appropriate drug for patients expected to obtain the therapeutic effect by using biomarkers and diagnostic tools.

About The Lancet Oncology

The Lancet Oncology is one of the most prestigious medical journals in the oncology field around the world.