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Chugai Obtains Approval for Expanded Use of FoundationOne CDx Cancer Genomic Profile as a Companion Diagnostic of Rozlytrek for ROS1-positive Lung Cancer

- Obtained approval as a companion diagnostic of Rozlytrek for *ROS1* fusion-positive non-small cell lung cancer (NSCLC), whose regulatory application is under review
- *ROS1* fusion gene is a cancer-driver gene found in approximately 1-2% of NSCLC cases

TOKYO, December 26, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained an approval for the expanded use of FoundationOne® CDx Cancer Genomic Profile as a companion diagnostic for anti-cancer agent/tyrosine kinase inhibitor, Rozlytrek® (generic name: entrectinib) for the treatment of *ROS1* fusion-positive, locally advanced or metastatic non-small cell lung cancer (NSCLC) from the Ministry of Health, Labour and Welfare on December 25, 2019. The approval allows physicians to identify NSCLC patients who could benefit from Rozlytrek by detecting *ROS1* fusion genes. Chugai filed an application for this additional indication of Rozlytrek for the treatment of *ROS1* fusion-positive, locally advanced or metastatic NSCLC on March 15, 2019.

"We are pleased that the FoundationOne CDx Cancer Genomic Profile is now approved as a companion diagnostic against *ROS1* fusion gene, which is one of the driver mutations in NSCLC. Although the frequency of *ROS1* fusion gene expression in NSCLC is only about 1 to 2%[1)], treatment using ROS1 inhibitors can become one of the important therapeutic options for patients with ROS1-positive cancer," said Dr. Minoru Watanabe, Chugai's Vice President, Head of Foundation Medicine Unit. "I am convinced that comprehensive cancer genomic profiling can further contribute to patients by enhancing its companion diagnostic functions. We will further expand companion diagnostic functions for both our in-house products and collaborations with biopharma partners."

Developed by Foundation Medicine Inc., FoundationOne CDx Cancer Genomic Profile is a next-generation sequencing based *in vitro* diagnostic device for the detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. The program is available as a companion diagnostic for multiple molecular-targeted drugs approved in Japan.

As a leading company in the field of oncology, Chugai is committed to realize advanced personalized oncology care and contribute to patients and healthcare professionals through improving access to comprehensive genomic profiling.

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[Note]
A press release issued on March 15, 2019: Chugai Files a New Drug Application for a ROS1/TRK Inhibitor Entrectinib for the Treatment of *ROS1* Fusion-Positive Non-Small Cell Lung Cancer
https://www.chugai-pharm.co.jp/english/news/detail/20190315160001_601.html

Approval information The underlined part has been newly added.

Intended uses or indications

- The Product is used for comprehensive genomic profiling of tumor tissues in patients with solid cancers.
- The Product is used for detecting gene mutations and other alterations to support the assessment of drug indications listed in the table below.

Alterations	Cancer type	Relevant drugs
EGFR exon 19 deletions and *EGFR* exon 21 L858R alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib
ERBB2 copy number alterations (*HER2* gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
KRAS/*NRAS* wild-type	Colorectal cancer	cetuximab (genetical recombination), panitumumab (genetical recombination)
NTRK1/2/3 fusion gene	Solid tumors	entrectinib
BRCA1/2 alterations	Ovarian cancer	olaparib

About Rozlytrek
Rozlytrek is an oral tyrosine kinase inhibitor that blocks ROS1 (c-ros oncogene 1) and TRK (neurotrophin receptors) family strongly and selectively. It blocks ROS1 and TRK kinase activity, and inhibits proliferation of cancer cells with *ROS1* or *NTRK* gene fusions. Chugai obtained approval of Rozlytrek for the treatment *NTRK* fusion-positive advanced or recurrent solid tumors on June 18, 2019 and launched the product on September 4, 2019 in Japan.

[Reference]
1: Bergethon K, Shaw AT, Ou SH, et al. *ROS1* rearrangements define a unique molecular class of lung cancers. J Clin Oncol 2012;30:863-70.

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