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Chugai Files for Expanded Use of FoundationOne CDx Cancer Genomic Profile as a Companion Diagnostic of Rozlytrek for *ROS1*-Positive NSCLC

- Aiming to develop a companion diagnostic of Rozlytrek for *ROS1* fusion-positive non-small cell lung cancer (NSCLC) currently under regulatory review
- The prevalence of *ROS1* fusion gene rearrangement in NSCLC is 1-2% [1,2]

TOKYO, September 6, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it filed an application with the Ministry of Health, Labour and Welfare (MHLW) for expanded use of FoundationOne® CDx Cancer Genomic Profile, a next-generation sequencing based program, as a companion diagnostic for ROS1/TRK inhibitor, Rozlytrek® Capsules 100 mg and 200 mg (generic name: entrectinib) for the treatment of *ROS1* fusion-positive non-small cell lung cancer (NSCLC).

The filing aims to expand the program for use as a companion diagnostic to identify people that could potentially benefit from Rozlyterk for the treatment of *ROS1* fusion-positive locally advanced or metastatic NSCLC by detecting the *ROS1* gene fusions using next-generation sequencer. *ROS1* fusion gene is an abnormal gene that can be formed by fusing the *ROS1* gene and other genes (*CD74*, etc.) as a result of chromosomal translocation for some reason. The *ROS1* fusion kinase made from *ROS1* fusion gene is considered to promote cancer cell proliferation.[2] The *ROS1* fusion gene is prevalent in about 1-2% of non-small cell lung cancer, among them, it is more expressed in adenocarcinoma. [1, 2]

Rozlytrek was granted regulatory approval by MHLW for the treatment of *NTRK* fusion gene positive advanced and recurrent solid tumors on June 18, 2019 and the drug has been launched on September 4. An application has been filed with the MHLW for the extended indication of *ROS1* fusion-positive NSCLC on March 15, 2019.

FoundationOne CDx Cancer Genomic Profile is a next-generation sequencing based *in vitro* diagnostic device developed by Foundation Medicine Inc. The product detects 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 was approved to use as a companion diagnostic for 14 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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[Notes]
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

About Rozlytrek

Rozlytrek is an oral medicine for the treatment of locally advanced or metastatic solid tumors that harbor *NTRK1*/2/3 or *ROS1* gene fusions. It is a selective tyrosine kinase inhibitor designed to inhibit the kinase activity of the TRK A/B/C and ROS1 proteins, whose activating fusions drive proliferation in certain types of cancer. FDA has approved Rozlytrek for people with *ROS1*-positive, metastatic NSCLC and NTRK gene fusion-positive solid tumors. Rozlytrek was granted Priority Medicines (PRIME) designation by the European Medicines Agency (EMA).

References

1. Davies KD, Doebele RC. *Clin Cancer Res.* 2013;19(15):4040-4045. PMID: 23719267
2. Bergethon K, Shaw AT, Ou SH, et al. *J Clin Oncol.* 2012;30(8):863-870. PMID: 22215748

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