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Chugai Obtains Approval for Expanded Use of FoundationOne CDx Cancer Genomic Profile as a Companion Diagnostic of Larotrectinib for *NTRK* Gene Fusion Positive Solid Tumors

- FoundationOne CDx Cancer Genomic Profile approved for expanded use as a companion diagnostic of larotrectinib
- Bayer Yakuhin, Ltd. has submitted an application of larotrectinib for the treatment of patients with solid tumors harboring a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion to the MHLW

TOKYO, January 25, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained approval from the Ministry of Health, Labour and Welfare (MHLW) on January 22, 2021 for the expanded use of FoundationOne® CDx Cancer Genomic Profile as a companion diagnostic (CDx) for the tropomyosin receptor kinase (TRK) inhibitor, larotrectinib developed for the treatment of patients with solid tumors harboring a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion, also known as TRK fusion cancer.

“Chugai aims to advance personalized healthcare and it is an important step for us that FoundationOne CDx Cancer Genome Profile received approval as a companion diagnostic for larotrectinib, which was developed for the treatment of cancer patients with an *NTRK* gene fusion, a rare genomic alteration,” said Dr. Osamu Okuda, Chugai’s President and COO. “We are committed to broaden the adaptation of this genomic profiling so that as many patients as possible can receive the appropriate treatment for the disease.”

This approval expands the use of FoundationOne CDx Cancer Genomic Profile as a companion diagnostic to identify patients with TRK fusion cancer who could benefit from treatment with larotrectinib. The efficacy and safety of larotrectinib were investigated in the multiple clinical trials conducted by Bayer; a phase I trial in adult patients, the phase II NAVIGATE trial in adult and adolescent patients, and the phase I/II pediatric SCOUT trial. Bayer Yakuhin, Ltd. submitted an application for marketing authorization of larotrectinib for the treatment of patients with solid tumors harboring an *NTRK* gene fusion to the MHLW on May 22, 2020.

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

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

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
Activated *EGFR* 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
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
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, larotrectinib sulfate
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib

About FoundationOne CDx Cancer Genomic Profile

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.

About larotrectinib

Larotrectinib, an oral selective TRK inhibitor, was exclusively designed to treat tumors that have an *NTRK* gene fusion. Larotrectinib was granted Orphan Drug Designation by the Ministry of Health, Labour and

Welfare for the expected indication of “Locally advanced or metastatic solid tumor harboring an *NTRK* gene fusion.”

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