

Innovation all for the patients



Roche A member of the Roche group

Chugai Files for Expanded Use of FoundationOne CDx Cancer Genomic Profile as a Companion Diagnostic of Larotrectinib for TRK Fusion Cancer

- Filed for expanded use as a companion diagnostic of larotrectinib for the treatment of TRK fusion cancer

TOKYO, October 2, 2020 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that it filed an application with the Ministry of Health, Labour and Welfare (MHLW) for the expanded use of FoundationOne® CDx Cancer Genomic Profile as a companion diagnostic (CDx) for the tropomyosin receptor kinase (TRK) inhibitor, larotrectinib for the treatment of tropomyosin receptor kinase fusion cancer on July 30, 2020.

“Neurotrophic tyrosine receptor kinase (*NTRK*) gene fusions are rare and occur across various tumor types regardless of age. Comprehensive genomic profiling is a useful tool for detecting this rare fusion gene,” said Dr. Osamu Okuda, Chugai’s President and COO. “We hope FoundationOne CDx Cancer Genomic Profile will become available as a CDx for larotrectinib with this filing and will promote advanced personalized healthcare by providing information that can support informed treatment decisions for more patients.”

FoundationOne CDx evaluates substitutions, insertion and deletion alterations (indels), and copy number alteration in 324 genes and select gene rearrangements, inclusive of gene fusions. The filing aims to expand the use of FoundationOne CDx Cancer Genomic Profile as a CDx to identify patients who could benefit from larotrectinib for the treatment of TRK fusion cancer by detecting *NTRK* gene fusions which produces the TRK fusion protein across solid tumors. The efficacy and safety of larotrectinib was investigated in clinical trials conducted by Bayer; phase I trial of 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 of larotrectinib for the treatment of TRK fusion cancer 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.

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, a specific oral 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”.

Trademarks used or mentioned in this release are protected by laws.

###