Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Chugai Obtains Approval for FoundationOne CDx Cancer Genomic Profile to Be Used as a Companion Diagnostic for RET Receptor Tyrosine Kinase Inhibitor, Selpercatinib for *RET* Fusion-Positive Solid Tumors

- FoundationOne CDx Cancer Genomic Profile obtained approval as a companion diagnostic for *RET* fusion genes, a rare oncogenic driver in several cancers
- The product has companion diagnostic functions in 8 cancer types in which the *RET* fusions come as the fourth alteration to obtain a tumor agnostic CDx approval

TOKYO, February 29, 2024 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it has obtained approval from the Ministry of Health, Labour and Welfare (MHLW) on February 28, 2024, for FoundationOne®CDx Cancer Genomic Profile to be used as a companion diagnostic for Eli Lilly Japan K.K.'s RET (rearranged during transfection) receptor tyrosine kinase inhibitor, Retevmo capsules (generic name: selpercatinib), for *RET* fusion-positive solid tumors.

"We are pleased that FoundationOne CDx Cancer Genomic Profile was approved as a companion diagnostic for selpercatinib, a cancer therapeutic drug for a rare *RET* fusion gene. It is useful for smooth consideration of treatment plans for patients because it can diagnose with a single test, including extremely rare genetic mutations that are found to be expressed across cancer types," said Chugai's President and CEO, Dr. Osamu Okuda.

This approval enables the detection of *RET* fusion genes using the FoundationOne CDx Cancer Genome Profile to assist of the decision to use selpercatinib for *RET* fusion-positive solid tumors. The efficacy and safety of selpercatinib for *RET* fusion-positive solid tumors was evaluated in the LIBRETTO-001 Phase 1/2 study. Eli Lilly Japan K.K. is currently applying to the MHLW for additional indications.

As a leading company in the field of oncology, Chugai is committed to realizing advanced personalized healthcare in oncology and contributing to patients through the expansion of Comprehensive Genome Profile.

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 and bolded 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, dacomitinib hydrate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib, brigatinib
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, encorafenib, binimetinib
ERBB2 copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
AKT1 alterations		capivasertib
PIK3CA alterations		
PTEN alterations		
KRAS/*NRAS* wild-type	Colorectal cancer	cetuximab (genetical recombination), panitumumab (genetical recombination)
Microsatellite instability high		nivolumab (genetical recombination)
Microsatellite instability high	Solid tumors	pembrolizumab (genetical recombination)
Tumor mutational burden high		pembrolizumab (genetical recombination)
NTRK1/2/3 fusion gene		entrectinib, larotrectinib sulfate
***RET* fusion genes**		**selpercatinib**

Alterations	Cancer type	Relevant drugs
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib, talazoparib tosilate
FGFR2 fusion genes	Biliary tract cancer	pemigatinib

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.

###