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Chugai Obtains Regulatory Approval for FoundationOne CDx Cancer Genomic Profile to be Used as Companion Diagnostic of Four Drugs for the Treatment of Non-Small Cell Lung Cancer and Malignant Melanoma

- As a treatment decisions support, the expansion of companion diagnostic (CDx) portfolio will provide further value for patients and improve access to cancer treatments
- Chugai aims to further contribute to advancing cancer treatment by pursuing additional CDx indications

TOKYO, June 3, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) on June 2, 2022 for FoundationOne® CDx Cancer Genomic Profile to be used as a companion diagnostic (CDx) for non-small cell lung cancer (NSCLC) therapies, a tyrosine kinase inhibitor VIZIMPRO® tablets (generic name: dacomitinib hydrate) and a tyrosine kinase inhibitor ALUNBRIG® tablets (generic name: brigatinib), as well as for malignant melanoma therapies, a BRAF inhibitor BRAFTOVI® capsules (generic name: encorafenib) and a MEK inhibitor MEKTOVI® tablets (generic name: binimetinib).

“With a single test, FoundationOne CDx Cancer Genomic Profile can identify genomic alterations of each patient’s cancer comprehensively. This enables them to develop treatment plans tailored to the individual patients, realizing advanced personalized healthcare,” said Dr. Osamu Okuda, Chugai’s President and CEO. “We believe this portfolio expansion of companion diagnostics for four molecular-targeted drugs approved in Japan for the treatment of NSCLC and melanoma, will increase its value as a decision support and contribute to improved treatment access for patients with these types of cancer. We aim to further contribute to advancing cancer treatment by pursuing additional companion diagnostic indications.”

As a companion diagnostic, FoundationOne CDx Cancer Genomic Profile will be used to identify patients with activated *EGFR* alteration positive or *ALK* fusion gene positive NSCLC who may benefit from dacomitinib hydrate or brigatinib, respectively. It will also be used to identify patients with *BRAF* alteration positive malignant melanoma who may benefit from encorafenib and binimetinib combination.

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

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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, 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)
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
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib
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.

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