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Chugai Obtains Regulatory Approval for FoundationOne CDx Cancer Genomic Profile to be Used as a Companion Diagnostic for MSI-High Tumors

- FoundationOne CDx Cancer Genomic Profile was approved as a companion diagnostic for nivolumab and pembrolizumab for the treatment of patients with microsatellite instability high (MSI-High) tumors

TOKYO, June 22, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained approval from the Ministry of Health, Labour and Welfare (MHLW) on June 21, 2021, for FoundationOne®CDx Cancer Genomic Profile to be used as a companion diagnostic (CDx) for both a human anti-human PD-1 monoclonal antibody, Opdivo® [generic name: nivolumab (genetical recombination)] and a humanized anti-human PD-1 monoclonal antibody, Keytruda® [generic name: pembrolizumab (genetical recombination)] for the treatment of patients with microsatellite instability high (MSI-High) tumors.

“High microsatellite instability has been identified in tumors in various organs, and immune-checkpoint inhibitors can be a therapeutic option. FoundationOne CDx Cancer Genomic Profile is characterized by the ability to comprehensively capture information on individual gene alterations, as well as the ability to detect microsatellite instability,” said Dr. Osamu Okuda, Chugai’s President and CEO. “Through testing with FoundationOne CDx Cancer Genomic Profile, we will contribute to ensuring as many patients as possible to have access to optimal treatments.”

As a companion diagnostic, FoundationOne CDx Cancer Genomic Profile will be used to identify patients with MSI-High unresectable advanced or recurrent colorectal cancer that have progressed following chemotherapy who may benefit from nivolumab. It will also be used to identify patients with microsatellite instability (MSI-H) solid tumors that have advanced or relapsed after chemotherapy (limited to use when difficult to treat with standard of care), who may benefit from pembrolizumab.

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

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.

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

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)
Microsatellite instability high		nivolumab (genetical recombination)
Microsatellite instability high	Solid tumors	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.

About Microsatellite instability high (MSI-High)

The genome contains several short strings of DNA (deoxyribonucleic acid) called microsatellites that are repeated many times. High-frequency microsatellite instability (MSI-High) is an abnormal number of microsatellite repeats[1)]. Abnormal microsatellites do not lead to cancer, but tissues that show MSI-High are thought to be more likely to develop cancer. MSI-High has been found in patients with cancer of various organs, including endometrial, gastric, small intestine, colorectal, ovarian, renal pelvis/ureteral, prostate,

and breast cancers[2, 3]. MSI-High is also a hallmark of people with Lynch syndrome who are born with genomic alterations that predispose them to developing cancer[3].

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[Reference]

1. Nojadeh, J.N. et al.: Microsatellite instability in colorectal cancer. EXCLI J. 17: 159-168, 2018.
2. Japan Society of Cancer Therapy/Japanese Society of Clinical Oncology: Guidelines for Transversal Genomic Practice in Organs in Adult and Pediatric Advanced Solid Tumors, Second Edition, October 2019
3. Colorectal Cancer Study Group: Hereditary Colorectal Cancer Guidelines 2020 Version

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