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Chugai Obtains Approval for FoundationOne CDx Cancer Genomic Profile to Be Used as a Companion Diagnostic for PARP Inhibitor, Talazoparib, Which is Approved for *BRCA* Gene Mutation-Positive Castration-Resistant Prostate Cancer with Distant Metastases

- FoundationOne CDx Cancer Genomic Profile obtained approval as a companion diagnostic for Pfizer Japan Inc.'s talazoparib
- As a result, it has companion diagnostic functions for 8 cancer types and 25 drugs

TOKYO, February 5, 2024 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it has obtained approval from the Ministry of Health, Labour and Welfare (MHLW) on February 2, 2024, for FoundationOne® CDx Cancer Genomic Profile to be used as a companion diagnostic for Pfizer Japan Inc's polyadenosine 5' diphosphate ribose polymerase (PARP) inhibitor, TALZENNA capsules (generic name: talazoparib tosilate), which is approved for *BRCA* gene mutation-positive castration-resistant prostate cancer with distant metastases.

"We are pleased that FoundationOne CDx Cancer Genomic Profile was approved as a companion diagnostic for talazoparib for *BRCA* gene mutation-positive castration-resistant prostate cancer with distant metastases," said Chugai's President and CEO, Dr. Osamu Okuda. "Castration-resistant prostate cancer is considered an advanced cancer that is difficult to treat, and there is a high unmet medical need. By expanding companion diagnostics, we aim to increase the value of this test for smooth consideration of treatment plans, improve access for prostate cancer patients, and contribute to the advancement of cancer treatment."

This approval enables the detection of *BRCA1/2* gene mutations using the FoundationOne CDx Cancer Genome Profile to assist of the decision to use talazoparib for *BRCA* gene mutation-positive castration-resistant prostate cancer with distant metastases. The efficacy and safety of combination therapy of talazoparib and enzalutamide* for *BRCA* gene mutation-positive castration-resistant prostate cancer with distant metastases was evaluated in the global phase III study TALAPRO-2. Pfizer Japan Inc. obtained approval from the MHLW on January 18th, 2024.

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.

* Enzalutamide is the generic name of Xtandi tablets, a prostate cancer treatment drug for which Astellas Pharma Inc. has manufacturing and marketing approval.

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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)
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, **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.

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