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Chugai Obtains Approval for FoundationOne CDx Cancer Genomic Profile to Be Used as a Companion Diagnostic for the AKT Inhibitor, Capivasertib for Advanced HR-positive, HER2-negative Breast Cancer with *PIK3CA, AKT1* or *PTEN* Alterations

- FoundationOne CDx Cancer Genomic Profile obtained approval in Japan as the first companion diagnostic to identify three specific biomarker alterations (*PIK3CA, AKT1* and *PTEN*) present in approximately 50%[1,2,3] of advanced hormone receptor (HR)-positive breast cancers
- As a result, the product now serves as a companion diagnostic in 8 cancer types, 18 genes, and 27 drugs

TOKYO, March 27, 2024 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it has obtained approval from the Ministry of Health, Labour and Welfare (MHLW) on February 20, 2024, for FoundationOne®CDx Cancer Genomic Profile to be used as a companion diagnostic to identify patients eligible for AstraZeneca K.K.'s AKT inhibitor, Truqap tablets (generic name: capivasertib), in combination with Faslodex (generic name: fulvestrant) for patients with advanced unresectable or recurrent HR-positive, HER2-negative breast cancer with specific *PIK3CA, AKT1* or *PTEN* alterations, which was approved by the MHLW on March 26, 2024.

“We are very pleased that FoundationOne CDx Cancer Genomic Profile was approved as a companion diagnostic for capivasertib, a cancer agent for three alterations (*PIK3CA*, *AKT1* and *PTEN*) in breast cancer. By using this test as a companion diagnostic, approximately half of patients[1,2,3] with advanced HR-positive, HER2-negative breast cancer will be able to consider a more appropriate treatment option. We will continue to contribute to the advancement of personalized healthcare based on the patient's genetic mutation status by expanding companion diagnostics,” said Chugai’s President and CEO, Dr. Osamu Okuda.

This approval enables the detection of *PIK3CA, AKT1* and *PTEN* alterations using the FoundationOne CDx Cancer Genomic Profile to guide the decision to use capivasertib in combination with faslodex for advanced HR-positive, HER2-negative breast cancer patients with tumors harbouring these alterations. The efficacy and safety of the combination therapy of capivasertib and fulvestrant* in this specific form of breast cancer was evaluated in the global phase III CAPItello-291 study[4]. AstraZeneca K.K. obtained approval from the MHLW on March 26, 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.

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* Fulvestrant is the generic name of the breast cancer agent "FASLODEX" for which AstraZeneca K.K. has manufacturing and marketing approval.

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
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.

Sources

1. Howell S J, et al. Fulvestrant plus capivasertib versus placebo after relapse or progression on an aromatase inhibitor in metastatic, oestrogen receptor-positive, HER2-negative breast cancer (FAKTION). J Clin Oncol. 2022; 23:851-64.
2. Hortobagyi G N, et al. Correlative Analysis of Genetic Alterations and Everolimus Benefit in Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer: Results From BOLERO-2. J Clin Oncol. 2016; 34:419-26.
3. Millis S Z, et al. Landscape of phosphatidylinositol-3-kinase pathway alterations across 19784 diverse solid tumors. JAMA Oncol. 2016;2(12):1565-73.
4. Turner N, et al. Capivasertib in Hormone Receptor–Positive Advanced Breast Cancer. NEJM. 2023; 388:2058–70.

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