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Chugai Obtains Approval for the Expanded Use of FoundationOne CDx Cancer Genomic Profile as a Companion Diagnostic for Lynparza

- Additional approval was granted as a companion diagnostic of Lynparza for ovarian cancer
- First approved companion diagnostic in Japan to detect tumor *BRCA* mutation including both germline (inherited) and somatic (acquired) mutations
- FoundationOne CDx is now approved in Japan as a companion diagnostic for 15 therapies

TOKYO, September 25, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained the approval of expanded use of FoundationOne® CDx Cancer Genomic Profile as a companion diagnostic for anti-tumor agent/PARP inhibitor Lynparza® (generic name: olaparib) for the maintenance treatment after 1st line chemotherapy in patients with BRCA-mutated advanced ovarian cancer from the Ministry of Health, Labour and Welfare (MHLW). With this approval, Foundation One CDx Cancer Genomic Profile will be available in Japan as a companion diagnostic for 15 therapies.

The approval allows physicians to identify patients with BRCA-mutated advanced ovarian cancer who could benefit from Lynparza as a maintenance treatment after 1st line chemotherapy by detecting *BRCA1/2* gene mutations. In Japan, AstraZeneca (LSE/STO/NYSE: AZN) has obtained approval for an additional indication of maintenance treatment after 1st line chemotherapy in patients with BRCA-mutated ovarian cancer for Lynparza from the MHLW on June 19, 2019.[1)] Under the global strategic oncology collaboration between AstraZeneca and MSD (NYSE: MRK), the two company has jointly commercialized Lynparza in Japan.

“We are pleased that FoundationOne CDx Cancer Genomic Profile has been approved as a companion diagnostic for Lynparza in certain patients with advanced ovarian cancer,” said Dr. Minoru Watanabe, Chugai’s Vice President, Head of Foundation Medicine Unit. “The program is the first MHLW-approved companion diagnostic which can detect *BRCA* alterations including both germline and somatic mutations in Japan.[*] We are committed to improve patient access for optimal treatment through the program.”

“The approval of FoundationOne CDx Cancer Genomic Profile as a companion diagnostic for Lynparza (olaparib) in women with ovarian cancer represents significant progress in delivering precision medicine to more Japanese patients via our strong collaboration with Foundation Medicine Inc. and Chugai Foundation Medicine Unit.,” said Ruth March, Ph.D., Senior Vice President and Head of Precision Medicine, Oncology R&D, AstraZeneca.

Developed by Foundation Medicine Inc., FoundationOne CDx Cancer Genomic Profile is a next-

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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 molecular-targeted drugs approved in Japan.

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

* FoundationOne CDx Cancer Genome Profile detects *BRCA* mutation including both germline (inherited) and somatic (acquired) mutations, but its report does not provide information on the origin of mutation.

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
EGFR exon 19 deletions and *EGFR* exon 21 L858R 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
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)
NTRK1/2/3 fusion gene	Solid tumors	entrectinib
BRCA1/2 alterations	Ovarian cancer	olaparib

[Reference]

1. Lynparza approved in Japan for 1st-line maintenance therapy in BRCA-mutated advanced ovarian cancer. Press release issued by AstraZeneca on June 19,

2019. https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2019/lynparza-approved-in-japan-for-1st-line-maintenance-therapy-in-brca-mutated-advanced-ovarian-cancer-19062019.html (Accessed on September, 2019)

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