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Chugai Files an Application for Expanded Use of Genomic Mutation Analysis Program “FoundationOne CDx Cancer Genomic Profile” as a Companion Diagnostic of Lynparza

- Aiming to develop a companion diagnostic of Lynparza for the treatment of ovarian cancer

TOKYO, March 29, 2019 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that it filed an application with the Ministry of Health, Labour and Welfare (MHLW) for expanded use of “FoundationOne® CDx Cancer Genomic Profile,” a next-generation sequencing based program currently under preparation for launch, to include as a companion diagnostic using tumor tissue specimens for PARP inhibitor “Lynparza®” (generic name: olaparib).

The filing aims to expand the program for use as a companion diagnostic to identify people that could potentially benefit from Lynparza for the maintenance treatment of adult patients with advanced ovarian cancer in complete or partial response to first-line platinum-based chemotherapy who have tumor mutations in *BRCA1/2* based on the SOLO-1 Phase 3 randomized trial results.

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 was approved by the MHLW in December 2018 as the first cancer genomic test in Japan with the two functions of cancer genomic profiling and companion diagnostics for molecular-targeted drugs.

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.

[Notes]

A press release issued on December 27, 2018: Chugai Obtains Approval for Genomic Mutation Analysis Program “FoundationOne CDx Cancer Genomic Profile”

https://www.chugai-pharm.co.jp/english/news/detail/20181227163000_583.html

About FoundationOne CDx Cancer Genomic Profile

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. FoundationOne CDx Cancer Genomic Profile is intended to be used as a comprehensive companion diagnostic for patients with certain types of cancers to identify those patients that may benefit from approved molecular targeted therapies in Japan.

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