Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Chugai Obtains Approval for FoundationOne Liquid CDx Cancer Genomic Profile to be used as a Companion Diagnostic for Olaparib in *BRCA*-Mutated Prostate Cancer

- FoundationOne Liquid CDx Cancer Genomic Profile has been approved for use as a companion diagnostic for olaparib in advanced prostate cancer
- With both FoundationOne CDx Cancer Genomic Profile and FoundationOne Liquid CDx Cancer Genomic Profile approved as companion diagnostics for olaparib, both tissue and liquid-based tests can be used to identify patients who may be eligible for this treatment option

TOKYO, May 20, 2021 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it has obtained approval from the Ministry of Health, Labour and Welfare (MHLW) on May 19, 2021 for FoundationOne®Liquid CDx Cancer Genomic Profile to be used as a companion diagnostic for the PARP inhibitor, Lynparza® (generic name: olaparib) for the treatment of *BRCA*-mutated castrate-resistant prostate cancer (mCRPC) with distant metastasis. With this approval, patients with advanced prostate cancer who may be eligible for the treatment with olaparib can be identified through both tissue-based and liquid-based comprehensive genomic profiling (CGP) tests. Since tissue availability can be an issue for some metastatic prostate cancer patients, blood-based testing is an important option to consider and critically important for informing patient care.

"We are pleased that the FoundationOne Liquid CDx Cancer Genomic Profiletest was approved as a companion diagnostic for olaparib for advanced metastatic prostate cancer, following the tissue-based FoundationOne CDx Cancer Genomic Profile approval in December last year," said Chugai's President and CEO, Dr. Osamu Okuda. "Precision cancer medicine is rapidly changing the treatment strategy for mCRPC and it is very important to understand the genomic profile of a patient's tumor in order to select the optimal treatment. The availability of both liquid and tissue-based companion diagnostics helps to identify patients who may be eligible for olaparib. We are committed to advancing personalized healthcare in cancer treatment."

The approval aims to expand the use of FoundationOne Liquid CDx Cancer Genomic Profile as a companion diagnostic for olaparib in advanced prostate cancer which progressed after treatment with enzalutamide or abiraterone. It identifies patients who my be eligible for the treatment by detecting *BRCA1/2* gene alterations. The efficacy and safety of olaparib in mCRPC patients with *BRCA1/2* alterations were investigated in the Phase III PROfound study and AstraZeneca K.K. received approval from the MHLW on December 25, 2020. Olaparib is jointly developed and commercialized by AstraZeneca (LSE/STO/Nasdaq: AZN) and MSD (Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA).

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

As a leading company in the field of oncology, Chugai is committed to realize advanced personalized healthcare in oncology and contributing to patients and healthcare professionals through improving access to CGP.

Approval information The underlined part has been newly added.

Intended uses or indications

- The Product is used for comprehensive genomic profiling of blood samples in patients with solid tumors.
- 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 mesilate
EGFR exon 20 T790M alterations		osimertinib mesilate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
NTRK1/2/3 fusion gene	Solid tumors	entrectinib
BRCA1/2 alterations	Prostate cancer	olaparib

About FoundationOne Liquid CDx Cancer Genomic Profile

Developed by Foundation Medicine Inc. based in Cambridge, USA, FoundationOne Liquid CDx Cancer Genomic Profile is a next-generation sequencing based *in vitro* diagnostic device using blood samples for advanced cancer patients with solid tumors. It is intended to identify genomic alterations in 324 cancer-related genes through detection of circulating tumor DNA (ctDNA) in blood. The test is approved by the MHLW for use in cancer genome profiling to report substitutions, insertion and deletion alterations, and select gene rearrangements for short variants in 324 genes. It is also indicated for use as a companion diagnostic to identify patients who may benefit from treatment with specific targeted therapies (listed in Table above of Intended uses or indications). For the latest information about the product, including companion diagnostic indications, please refer to the prescribing information.

About *BRCA* alterations

BRCA1 and *BRCA2* are human genes that produce proteins responsible for repairing damaged DNA and play an important role in maintaining the genomic stability of cells. When either of these genes is mutated or altered, such that its protein product either is not made or does not function correctly, DNA damage may not be repaired properly, and cells become unstable. As a result, cells are more likely to develop additional genomic alterations that can lead to cancer and confer sensitivity to PARP inhibitors including Lynparza.[1-4]

[Reference]

1. Kirby, M. (2011). Characterising the castration-resistant prostate cancer population: a systematic review. International Journal of Clinical Practice, 65(11), pp.1180-1192.
2. Wu J, et al. (2010) The role of BRCA1 in DNA damage response. Protein Cell. 2010;1(2):117-123.
3. Roy R, et al. (2012). BRCA1 and BRCA2: different roles in a common pathway of genome protection. Nat Rev Cancer. 2011;12(1):68-78. Published 2011 Dec 23. doi:10.1038/nrc3181.
4. Gorodetska I, et al. (2019). BRCA Genes: The Role in Genome Stability, Cancer Stemness and Therapy Resistance. J Cancer. 2019;10(9):2109-2127.

###