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Chugai Files for Expanded Use of FoundationOne CDx Cancer Genomic Profile as a Companion Diagnostic of Lynparza for Metastatic Castration-Resistant Prostate Cancer with HRR-Related Gene Alterations

- Filed a companion diagnostic of Lynparza for the treatment of metastatic castration-resistant prostate cancer with homologous recombination repair (HRR) related gene alterations

TOKYO, June 5, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it filed an application with the Ministry of Health, Labour and Welfare for the expanded use of FoundationOne® CDx Cancer Genomic Profile as a companion diagnostic for the PARP inhibitor, Lynparza® (generic name: olaparib), for the treatment of homologous recombination repair mutated (HRRm) metastatic castration-resistant prostate cancer (mCRPC).

“Currently, various approaches are progressing to investigate new treatments for patients with mCRPC who are resistant to hormonal therapy and genomic medicine could become an important treatment option,” said Dr. Osamu Okuda, Chugai’s President and COO. “Since HRR gene alterations are recognized to be identified in multiple genes, we believe FoundationOne CDx Cancer Genomic Profile will be a useful tool that can support physicians to identify patients who may benefit from treatment with Lynparza by comprehensively understanding patients’ genomic profiles.”

The filing aims to expand the use as a companion diagnostic to identify patients who could benefit from Lynparza for the treatment of mCRPC with HRR related gene alterations, and have progressed following prior treatment with enzalutamide or abiraterone by detecting HRR related gene alterations. The efficacy and safety of Lynparza in mCRPC patients were investigated in the Phase III PROfound study. Lynparza is jointly developed and commercialized by AstraZeneca (LSE/STO/NYSE: AZN) and MSD (MSD: known as Merck & Co. inside the US and Canada).

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.

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.

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