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Chugai Obtains Approval for FoundationOne Liquid CDx Cancer Genomic Profile, the First Blood-based Comprehensive Genomic Profiling Test for Solid Tumors in Japan

- With a new blood-based test in addition to the tissue-based FoundationOne CDx Cancer Genomic Profile, Chugai aims to offer comprehensive genomic profiling to a wider range of patients and realize advanced personalized healthcare based on genomic profile of a patient's tumor
- FoundationOne Liquid CDx Cancer Genomic Profile was approved for use as a CGP test covering 324 genes as well as a companion diagnostic to identify patients who may benefit from certain approved targeted therapies

TOKYO, March 23, 2021 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it has obtained approval from the Ministry of Health, Labour and Welfare (MHLW) for FoundationOne® Liquid CDx Cancer Genomic Profile as the liquid biopsy (LB) test that provides comprehensive genomic profiling (CGP) for solid tumors on March 22, 2021. The test was also approved for use as a companion diagnostic (CDx) for certain approved targeted therapies in Japan, making it the first MHLW-approved blood-based test with both CDx and solid tumor CGP indications.

"The approval of FoundationOne Liquid CDx Cancer Genomic Profile, a blood-based CGP option, has a significant meaning for Chugai that aims to advance personalized healthcare based on the genomic profile of a patient's tumor," said Chugai's President and CEO, Dr. Osamu Okuda. "In cancer treatment that continues to evolve day-to-day, it enables us to support a wider range of patients to help inform treatment decisions aligning the patient's status and stage of treatment by utilizing both tissue-based and blood-based tests. We are committed to preparing for the launch of the test as soon as possible and also will continue to expand companion diagnostic functions with the aim of maximizing the value provided to patients."

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 from advanced cancer patients with solid tumors. It identifies genomic alterations in 324 cancer-related genes through detection of blood circulating tumor DNA (ctDNA) in blood. FoundationOne Liquid CDx Cancer Genomic Profile provides an integrated test report informing alterations matched to MHLW-approved targeted therapies.

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.

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Approval information

<table>
<tr><td>Brand name</td><td>FoundationOne® Liquid CDx Cancer Genomic Profile</td></tr>
<tr><td>Japanese medical device nomenclature (JMDN)</td><td>・ Software for gene variants analysis (for cancer genome profiling)
・ Software for analysis of somatic cell gene variants (for eligibility identification of antineoplastic agents)</td></tr>
<tr><td>Intended uses or indications</td><td>・ 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.
<table>
<tr><th>Alterations</th><th>Cancer type</th><th>Relevant drugs</th></tr>
<tr><td>Activated EGFR alterations</td><td rowspan="4">Non-small cell lung cancer (NSCLC)</td><td>afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate</td></tr>
<tr><td>EGFR exon 20 T790M alterations</td><td>osimertinib mesilate</td></tr>
<tr><td>ALK fusion genes</td><td>alectinib hydrochloride, crizotinib, ceritinib</td></tr>
<tr><td>ROS1 fusion genes</td><td>entrectinib</td></tr>
<tr><td>NTRK1/2/3 fusion gene</td><td>Solid tumors</td><td>entrectinib</td></tr>
</table></td></tr>
<tr><td>Conditions for approval</td><td>1. The necessary measures must be taken to ensure that the product is used by a physician with adequate knowledge and experience of cancer genomic medicine at a medical institution with a cancer genome profiling-based medical system pursuant to the “Guidelines for the Development of Core Hospitals and Other Facilities for Cancer Genomic Medicine,” and in compliance with the scope and timing of testing stipulated in the most recent guidelines, etc., of relevant academic societies.
2. Appropriate procedures and controls to protect personal information and up-to-date security and privacy protection measures to prevent unauthorized access must be implemented for blood samples sent to the laboratory and for information obtained from these specimens.
3. Quality control of input data must be performed as described in the Remarks column of the attached Application Form. Any changes to the quality control of input data as described in the Remarks column of the Application Form (excluding minor changes specified by Order of the MHLW in Article 23-2-5, paragraph (15) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices [“the Act”]) must be approved by the MHLW Minister pursuant to Article 23-2-5, paragraph (15) of the Act. Note that this approval applies mutatis mutandis to the provisions of Article 23-2-5 paragraph (17), Article 23-2-6, and Article 23-2-7 of the Act.</td></tr>
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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 in 324 cancer-related genes through detection of blood circulating tumor DNA (ctDNA). 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.

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