Innovation all for the patients

CHUGAI

Roche A member of the Roche group

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

- FoundationOne Liquid CDx Cancer Genomic Profile is now available for use as a comprehensive genomic profiling test covering 324 genes as well as a companion diagnostic to identify patients who may benefit from certain approved targeted therapies across multiple cancer indications

TOKYO, August 2, 2021 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has launched FoundationOne® Liquid CDx Cancer Genomic Profile as a liquid biopsy-based comprehensive genomic profiling (CGP) test for solid tumor, following the product's listing on the national health insurance (NHI) reimbursement price list on August 1, 2021. In addition, SRL Inc., the clinical laboratory testing company has started providing testing services for the product today. FoundationOne Liquid CDx Cancer Genomic Profile was approved by the Ministry of Health, Labour and Welfare (MHLW) on March 22, 2021 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.

"We are very pleased that we can start providing FoundationOne Liquid CDx Cancer Genomic Profile, a blood-based CGP testing option for patients today. The test provides meaningful information that can help inform treatment for patients with advanced or recurrent cancer, which is especially valuable if they are not eligible for tissue-based CGP testing," said Chugai's president and CEO Dr. Osamu Okuda. "We are committed to advance personalized healthcare through expanding access to CGP testing."

Developed by Foundation Medicine Inc. based in Cambridge, USA, FoundationOne Liquid CDx Cancer Genomic Profile is a blood-based diagnostic test that uses next-generation sequencing. It identifies genomic alterations in 324 cancer-related genes for cancer patients with solid tumors through detection of blood circulating tumor DNA (ctDNA). 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 advance personalized healthcare in oncology and contributing to patients and healthcare professionals through improving access to CGP.

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

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 maleate, 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>
<tr><td>BRCA1/2 alteration</td><td>Prostate cancer</td><td>olaparib</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>
</table>

Date of NHI reimbursement price listing:	August 1, 2021

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 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.

###