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Chugai Obtains Approval for Genomic Mutation Analysis Program "FoundationOne® CDx Cancer Genomic Profile"

-- Japan's first program with two functions of cancer genomic profiling and companion diagnostics --

-- Toward the realization of treatment proposal based on patient's cancer genomic profile --

TOKYO, December 27, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for "FoundationOne® CDx Cancer Genomic Profile," a next-generation sequencing based program for the purpose of gene mutation analysis program (for use in cancer genome profiling) for solid tumors and somatic gene mutation analysis program (for use in assessing anticancer drug indications). This is the first cancer genomic test granted expedited review in May 2018 and approved by the MHLW with the two functions of cancer genomic profiling and companion diagnostics for molecular-targeted drugs.

As a function of comprehensive genomic profiling of cancer-related genes, FoundationOne CDx Cancer Genomic Profile allows to identify mutation status of 324 cancer-related genes for solid tumors at once by using the patient's tumor tissues. As a comprehensive companion diagnostic function, it can be used as a companion diagnostic for the domestically approved molecular-targeted drugs listed in the following table. The report provided from this program includes information that supports physicians' decisions to develop treatment strategies for patients, and provides a summary of gene-mutation data, information on the relevant molecular-targeted drugs, their approval status and ongoing clinical studies as well as the relevant references.

"It is said that cancer is a disease caused by gene mutation, and the gene mutation status is different from patient to patient. Clarifying the profile of each cancer enables us to understand the characteristics of cancer, and is very important in order to select appropriate treatment approaches," said Tatsuro Kosaka, Chugai's President and CEO. "The conventional concept of cancer treatment is based on the treatment for each tumor organ. However, we will have a completely new approach since comprehensive genomic profiling would provide tumor agnostic treatment tailored to each patient's gene mutation. In order to realize more advanced personalized healthcare through this paradigm shift, we seek to obtain the national health insurance reimbursement coverage for this program in view of the universal healthcare system in Japan in order to contribute to many healthcare professionals and patients."

"The approval of FoundationOne CDx in Japan is yet another testament to its validation and is critical to enabling patient access to comprehensive genomic profiling," said Melanie Nallicheri, chief business officer and head of biopharma at Foundation Medicine. "Similar to our FDA approval in the United States, the MHLW has approved FoundationOne CDx as a

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comprehensive genomic profiling tool for all solid tumors and a broad companion diagnostic, a first of its kind comprehensive diagnostic test for individuals living with cancer in Japan. This is also an important milestone for our biopharma partners who can leverage FoundationOne CDx to accelerate companion diagnostic development and improve access to personalized oncology care in Japan."

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 domestically approved molecular targeted therapies.

About Foundation Medicine Inc.

Foundation Medicine is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer. The company offers a full suite of comprehensive genomic profiling assays to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies, immunotherapies and clinical trials. Foundation Medicine's molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer. For more information, please visit https://www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

Approval information

<table>
<tr><td>Brand name</td><td>FoundationOne® CDx Cancer Genomic Profile</td></tr>
<tr><td>Nonproprietary name</td><td>・ Gene mutation analysis program (for use in cancer genome profiling)
・ Somatic gene mutation analysis program (for use in assessing anticancer drug indications)</td></tr>
<tr><td>Intended uses</td><td>・ The Product is used for comprehensive genomic profiling of tumor tissues in patients with solid cancers.
・ 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><td>Alterations</td><td>Cancer type</td><td>Relevant drugs</td></tr>
<tr><td>EGFR exon 19 deletions and EGFR exon 21 L858R alterations</td><td rowspan="2">Non-small cell lung cancer (NSCLC)</td><td>afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate</td></tr>
<tr><td>EGFR exon 20 T790M alterations</td><td>osimertinib mesylate</td></tr>
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<tr><td>ALK fusion genes</td><td></td><td>alectinib hydrochloride, crizotinib, ceritinib</td></tr>
<tr><td>BRAF V600E and V600K alterations</td><td>Malignant melanoma</td><td>dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib</td></tr>
<tr><td>ERBB2 copy number alterations (HER2 gene amplification positive)</td><td>Breast cancer</td><td>trastuzumab (genetical recombination)</td></tr>
<tr><td>KRAS/NRAS wild-type</td><td>Colorectal cancer</td><td>cetuximab (genetical recombination), panitumumab (genetical recombination)</td></tr>
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<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 tumor tissue specimens 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 (11) 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 (11) of the Act. Note that this approval applies mutatis mutandis to the provisions of Article 23-2-5 paragraph (13), Article 23-2-6, and Article 23-2-7 of the Act.</td></tr>
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