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Chugai Launches Genomic Mutation Analysis Program, FoundationOne CDx Cancer Genomic Profile

TOKYO, June 3, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has launched FoundationOne® CDx Cancer Genomic Profile, (hereafter "the Program") a next-generation sequencing based gene mutation analysis program. Also, SRL Inc. has started providing testing services for the Program today.

FoundationOne CDx is the first cancer genomic test in Japan which obtained regulatory approval for the two functions 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). The approval was granted by the Ministry of Health, Labour and Welfare on December 27, 2018.

"FoundationOne CDx Cancer Genomic Profile will open up a new horizon for personalized cancer care. I am delighted that the program is now available for patients and healthcare providers in Japan," said Tatsuro Kosaka, Chugai's President and CEO. "Through this program, Chugai will further strive to realize advanced and sustainable patient-centric healthcare by promoting access to treatments optimized to each patient."

Developed by Foundation Medicine Inc., FoundationOne CDx Cancer Genomic Profile is a next-generation sequencing based *in vitro* diagnostic device for the detection and analysis 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 patient's tumor tissues. As a comprehensive companion diagnostic function, it can be also used as a companion diagnostic for certain 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 providers through comprehensive genomic profiling.

[Notes]
A press release issued on March 19, 2019: Miraca and Chugai Enter into Business Partnership Agreement for "FoundationOne® CDx Cancer Genome Profile"
https://www.chugai-pharm.co.jp/english/news/detail/20190319150000_603.html

Approval information

Brand name	FoundationOne® CDx Cancer Genomic Profile
Nonproprietary	・ Gene mutation analysis program (for use in cancer genome profiling)

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<table>
<tr><td>name</td><td>・ Somatic gene mutation analysis program (for use in assessing anticancer drug indications)</td></tr>
<tr><td>Approval date</td><td>December 27, 2018</td></tr>
<tr><td>Intended uses or indications</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><th>Alterations</th><th>Cancer type</th><th>Relevant drugs</th></tr>
<tr><td>EGFR exon 19 deletions and EGFR exon 21 L858R alterations</td><td rowspan="3">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>
<tr><td>ALK fusion genes</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>
</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 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</td></tr>
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	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.

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