Company name: Miraca Holdings Inc.
Name of Representative: President & CEO Shigekazu ,Takeuchi
Code Number: 4544, 1st Section of Tokyo Stock Exchange

Company name: Chugai Pharmaceutical Co., Ltd.
Name of Representative: President & CEO Tatsuro Kosaka
Code Number: 4519, 1st Section of Tokyo Stock Exchange

Miraca and Chugai Enter into Business Partnership Agreement for "FoundationOne® CDx Cancer Genome Profile"

TOKYO, March 19, 2019 – Miraca Holdings Inc. (hereafter "Miraca") and Chugai Pharmaceutical Co., Ltd. (hereafter "Chugai") announced today that SRL Inc. (hereafter "SRL"), a consolidated subsidiary of Miraca, and Chugai have entered into a business partnership agreement for "FoundationOne® CDx Cancer Genome Profile," an analysis program for gene mutation marketed by Chugai. Under this agreement, SRL will provide commissioned testing services through "FoundationOne CDx Cancer Genome Profile" for medical institutions.

FoundationOne CDx Cancer Genomic Profile consists of two programs for the purposes of gene mutation analysis program (for use in cancer genome profiling) and somatic gene mutation analysis program (for use in assessing anticancer drug indications). 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 a single testing by using the patient's tumor tissue. As a comprehensive companion diagnostic function, it can be used as a companion diagnostic for the domestically approved molecular-targeted therapies listed in the following table. The test also analyzes genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB), biomarkers that are reported to predict the efficacy of cancer immunotherapies.

SRL internally established Cancer Genetics Strategy Office in January 2018, considering increasing demand related to cancer genetic medicine globally, and has been implementing various activities. SRL continues to reinforce the activities toward development of genetic medicine.

In March 2018, Chugai started the business operation in Japan to market products developed by Foundation Medicine Inc. which provides comprehensive genomic profiling testing, aiming at improving access to personalized oncology care in Japan. As a leading company in the field of oncology, Chugai will continue to contribute to the establishment and implementation of cancer genomic medicine.

The impact of this agreement on consolidated financials of Miraca for the business term ending in March 2019 and those of Chugai for the business term ending in December 2019 are expected not to be material.

About SRL

Since the establishment in 1970, SRL, Inc., a member of the Miraca Group, Japan-based leading healthcare group, has been providing comprehensive testing services as the largest commercial clinical laboratory in Japan. SRL carries out nearly 400,000,000 tests per year, covering a wide range of testing services including general/emergency testing, esoteric/research testing, companion diagnostics tests, genomic analysis, and etc. For more information, please visit http://www.srl-group.co.jp/.

About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area.
Additional information is available on the internet at https://www.chugai-pharm.co.jp/english/.

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 approved molecular-targeted therapies in Japan.

Approval information

Brand name	FoundationOne® CDx Cancer Genomic Profile
Nonproprietary name	・ Gene mutation analysis program (for use in cancer genome profiling) ・ Somatic gene mutation analysis program (for use in assessing anticancer drug indications)
Approval date	December 27, 2018

<table>
<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 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)
</td></tr>
</table>

	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.

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).

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