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Chugai Obtains Approval for FoundationOne Liquid CDx Cancer Genomic Profile to Be Used as a Companion Diagnostic for Novartis' MET Inhibitor, Capmatinib, Which Is Approved for *MET* Exon 14 Skipping Mutation-Positive Advanced and/or Recurrent Unresectable Non-Small Cell Lung Cancer

- FoundationOne Liquid CDx Cancer Genomic Profile obtained approval as a companion diagnostic for capmatinib, a treatment for advanced and/or recurrent unresectable non-small cell lung cancer
- With both FoundationOne CDx Cancer Genomic Profile and FoundationOne Liquid CDx Cancer Genomic Profile approved as companion diagnostics for capmatinib, either tissue and liquid-based tests can be used to identify patients who may be eligible for this treatment option

TOKYO, May 26, 2023 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it has obtained approval from the Ministry of Health, Labour and Welfare (MHLW) on May 25, 2023, for FoundationOne®Liquid CDx Cancer Genomic Profile to be used as a companion diagnostic for an anti-cancer agent/MET inhibitor, Tabrecta® (generic name: capmatinib hydrochloride hydrate) of Novartis Pharma K.K. (Novartis), which is approved for the treatment of *MET* exon 14 skipping mutation-positive advanced and/or recurrent unresectable non-small cell lung cancer (NSCLC). With this approval, patients with advanced NSCLC who may be eligible for treatment with capmatinib can be identified through both tissue-based and liquid-based comprehensive genomic profiling (CGP) tests.

"We are pleased that FoundationOne Liquid CDx Cancer Genomic Profile was approved as a companion diagnostic for capmatinib for advanced and/or recurrent unresectable NCSLC, in addition to the currently approved tissue-based FoundationOne CDx Cancer Genomic Profile," said Chugai's President and CEO, Dr. Osamu Okuda. "Obtaining tissue samples can be a challenge for patients with NSCLC. Therefore, blood-based testing is an important option when considering treatment options for patient care. We are committed to advancing personalized healthcare by continuing to collaborate with many biopharma partners."

With this approval FoundationOne Liquid CDx Cancer Genomic Profile can be used as a companion diagnostic for capmatinib in advanced and/or recurrent unresectable NSCLC. It identifies patients eligible for the treatment by detecting *MET* exon 14 skipping gene alterations. The efficacy and safety of capmatinib in patients with advanced and/or metastatic NSCLC patients with *MET* exon 14 skipping alterations were investigated in the Phase II GEOMETRY mono-1 study conducted by Novartis. Novartis received approval from the MHLW in June 2020 for commercialization.

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As a leading company in the field of oncology, Chugai is committed to realizing advanced personalized healthcare in oncology and contributing to patients through the expansion of CGP.

Approval information The underlined part has been newly added.

Intended uses or indications

- 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.

Alterations	Cancer type	Relevant drugs
Activated *EGFR* alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate
EGFR exon 20 T790M alterations		osimertinib mesilate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
NTRK1/2/3 fusion gene	Solid tumors	entrectinib
BRCA1/2 alterations	Prostate cancer	olaparib

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 the detection of circulating tumor DNA (ctDNA) in blood. The test is approved by the MHLW for use in cancer genome profiling to report alterations (substitutions, insertion/deletion 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 the Table above of Intended uses or indications). For the latest information about the product, including companion diagnostic indications, please refer to the approval information.

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