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Chugai Starts Activities towards Commercialization of Foundation Medicine's Products in Japan

-- Chugai Enters a License Agreement with Roche and Submits for Regulatory Approval of "FoundationOne CDx™" --

TOKYO, March 16, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519, Chugai) announced that it has entered into a sub-license agreement with F. Hoffmann-La Roche Ltd. (SIX: RO, ROG; OTCQX: RHHBY, Roche) for exclusive commercialization rights in Japan to a suite of comprehensive genomic profiling (CGP) assays developed by Foundation Medicine Inc. (NASDAQ:FMI). In accordance with this agreement, Chugai today filed for regulatory approval of "FoundationOne CDx™ (Overseas product name)" as a CGP test for all solid tumors to the Ministry of Health, Labour and Welfare (MHLW).

"Offering each patient the most appropriate treatment based on Personalized Healthcare (PHC) is becoming a reality, and entering the genomic analysis business, which may bring a paradigm shift for healthcare and treatment, will be a new challenge for us," said Chugai's President & COO, Tatsuro Kosaka. "Genomic analysis has significant synergies with pharmaceuticals, the focus of Chugai's core business. We are committed to contributing to healthcare and patients by developing Foundation Medicine's products in the Japanese market to further enhance the capabilities we have cultivated in the field of oncology. We will also accelerate R&D activities based on PHC by utilizing Foundation Medicine's molecular information platform."

Founded in 2010 in Cambridge, MA, USA, Foundation Medicine is a molecular information company focusing on genomic sequencing in oncology. In 2015, Roche and Foundation Medicine entered into a broad strategic collaboration in the field of oncology molecular information. Foundation Medicine offers genomic tests including FoundationOne® for solid tumors, FoundationOne®Heme for hematologic malignancies and sarcomas, FoundationACT®, a liquid biopsy assay for solid tumors and FoundationOne CDx™, the first FDA-approved CGP test for all solid tumors with multiple companion diagnostics, approved in November 2017.

FoundationOne CDx is a next-generation sequencing based in vitro diagnostic device for 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. In addition, Chugai is seeking approval for FoundationOne CDx to be used as a companion diagnostic for patients with certain types of cancers to identify those patients that may benefit from treatment with targeted therapies approved in Japan.

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Under the agreement, Chugai obtains an exclusive license for the commercialization of FMI's current suite of genomic profiling assays in Japan and is responsible for regulatory and commercialization activities in Japan. Per the terms of the agreement, Roche will receive an upfront fee from Chugai.

About Foundation Medicine Inc.

Foundation Medicine (NASDAQ:FMI) 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 http://www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

About FoundationOne CDx™

FoundationOne CDx is a next-generation sequencing based in vitro diagnostic device for 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 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 treatment with one of 17 targeted therapies following detection of alterations in the *EGFR*, *ALK*, *BRAF*, *ERBB2* (HER2), *KRAS*, *NRAS* and *BRCA1/2*. For the complete intended use statement, including companion diagnostic indications, please see the FoundationOne CDx Technical Information, www.foundationmedicine.com/f1cdx.

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