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Foundation Medicine Advances Patient Access to Precision Medicine; Pursues Regulatory Approval for FoundationOne CDx™ in Japan

-- Chugai to Commercialize Foundation Medicine's Suite of Comprehensive Genomic Profiling (CGP) Services in Japan, Expanding Patient Access to Personalized Cancer Care --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced that Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519), one of Japan's leading research-based pharmaceutical companies and a member of the Roche Group, will broaden patient access to Foundation Medicine's comprehensive genomic profiling (CGP) services for individuals with advanced cancer. Specifically, Chugai has filed for regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) in Japan for FoundationOne CDx™, which, if approved in Japan, would enable access to MHLW-approved targeted therapies and immunotherapies, as well as clinical trials, for patients with cancer in Japan. Chugai will also lead commercial efforts in Japan for Foundation Medicine's suite of CGP assays.

FoundationOne CDx is the first FDA-approved comprehensive genomic profiling (CGP) assay for all solid tumors that incorporates multiple companion diagnostics. If approved in Japan by the MHLW, Chugai will be the Marketing Authorization Holder of FoundationOne CDx in Japan.

"Seeking approval for FoundationOne CDx in Japan is an important step for the integration of comprehensive genomic profiling into oncology clinical care," said Melanie Nallicheri, chief business officer and head, biopharma for Foundation Medicine. "Importantly, an MHLW-approved assay could enable the same accelerated pathway for companion diagnostic development and approval that Foundation Medicine has pioneered in the United States with FDA approval, meeting a critical need today for our biopharma partners' global development and commercial efforts. We look forward to partnering with Chugai, and our biopharma partners, to expand MHLW-approved companion diagnostics claims on FoundationOne CDx ensuring patient access to personalized cancer care."

FoundationOne CDx assesses genomic alterations in 324 genes known to drive cancer growth, providing potentially actionable information to help guide treatment decisions. It is indicated for use by health care professionals to help inform cancer treatment management in accordance with professional guidelines for patients with solid tumors. The first FDA-approved test of its kind for all solid tumors, FoundationOne CDx is a diagnostic test that acts as: a broad companion diagnostic for patients who may benefit from treatment with specific FDA-approved targeted therapies; a CGP test that includes genomic biomarkers such as microsatellite instability (MSI) and tumor mutational burden (TMB), to help inform the use of other targeted oncology therapies, including immunotherapies; a tool for physicians that identifies patient opportunities for clinical trial participation; and, an FDA-approved platform for companion diagnostic development for biopharma companies developing precision therapeutics.

"This collaboration further enables us to pursue personalized oncology care in Japan," said Tatsuro Kosaka, Chugai's president and chief operating officer. "Regulatory approval for FoundationOne CDx would establish validation for the assay in Japan. We're excited to collaborate with Foundation Medicine to change the cancer care treatment paradigm in Japan."

Japan represents the fourth largest addressable market for next generation sequencing in oncology following the United States, China and Germany. The country accounts for approximately 9% of all global oncology costs. Approximately 52% of all oncology drugs approved globally between 2011-2015 are available in Japan.[1]

About FoundationOne CDx
FoundationOne CDx is a next generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) 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 as a companion diagnostic to identify patients who may benefit from treatment with certain targeted therapies in accordance with their approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. For a full list of targeted therapies for which FoundationOne CDx is indicated as a companion diagnostic, please visit http://www.foundationmedicine.com/genomic-testing/foundation-one-cdx.

About Foundation Medicine
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 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 unmet medical needs, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2017 of Chugai totaled 534.2 billion yen and the operating income was 103.2 billion yen (IFRS Core basis). Additional information is available on the internet at https://www.chugai-pharm.co.jp/english/.

Cautionary Note Regarding Forward-Looking Statements for Foundation Medicine
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding a collaboration between Foundation Medicine and Chugai; the scope and timing of any approval of FoundationOne CDx by the MHLW; the ability of a MHLW-approved FoundationOne CDx to enable access to MHLW-approved targeted therapies and immunotherapies, as well as clinical trials for patients with cancer in Japan; and the ability for an MHLW-approved assay to enable an accelerated pathway for companion diagnostic development and approval. All such forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include the risks that the collaboration does not proceed as expected or does not meet the objectives of the parties; a delay on the part of, or failure of, the MHLW to approve FoundationOne CDx; and the risks described under the caption "Risk Factors" in Foundation Medicine's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 7, 2018, as well as other risks detailed in Foundation Medicine's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Foundation Medicine undertakes no duty to update this information unless required by law.

[1] Global Oncology Trends 2017. Report by the QuintilesIMS Institute

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