March 30, 2018

Foundation Medicine Announces Commercial Availability of FoundationOne CDx™, the First FDA-Approved Comprehensive Genomic Profiling Assay for All Solid Tumors Incorporating Multiple Companion Diagnostics

-- FoundationOne CDx is the First Next Generation Sequencing Test for All Solid Tumors to Complete the FDA/CMS Parallel Review Process and Launch with National Medicare Coverage --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced that FoundationOne CDx™, the first U.S. Food and Drug Administration (FDA) approved comprehensive genomic profiling (CGP) assay for all solid tumors incorporating multiple companion diagnostics, is now available in the United States. FoundationOne CDx is a first-of-its-kind test for individuals with advanced cancer that is offered as a nationally covered benefit across all solid tumors for Medicare and Medicare Advantage beneficiaries who meet eligibility requirements.

"Now that FoundationOne CDx is widely available in the U.S., oncologists can begin using this valuable test to help guide and simplify personalized treatment decisions for their patients," Vincent Miller, M.D., chief medical officer at Foundation Medicine. "By integrating FoundationOne CDx early into routine clinical care, oncologists can create treatment efficiencies and expand access to biomarker-driven medicines for patients, with the potential to improve treatment outcomes."

Expanded access to clinically and analytically validated genomic profiling may establish a path toward improved patient outcomes. Personalized, biomarker-based therapy has been shown to be associated with clinical benefit across tumor types and biomarkers,[1] making therapy selection ever more complex. FoundationOne CDx offers treating physicians a single, FDA-approved comprehensive platform for all solid tumors to detect specific genomic alterations that help guide efficient, personalized treatment decisions, while reducing the time and tissue needed when testing for biomarkers one at a time.

FoundationOne CDx, an FDA-approved CGP assay for all solid tumors, assesses genomic alterations in 324 genes known to drive cancer growth, providing potentially actionable information to help guide treatment options. FoundationOne CDx is also FDA-approved as a broad companion diagnostic for patients with certain types of non-small cell lung cancer, melanoma, colorectal cancer, ovarian cancer or breast cancer to identify those patients who may benefit from treatment with one of 17 on-label targeted therapies, 12 of which are approved as first line therapy for their respective indications. FoundationOne CDx also reports genomic biomarkers, such as microsatellite instability (MSI) and tumor mutational burden (TMB), that can help inform the use of other targeted oncology therapies, including immunotherapies and relevant clinical trial information. In all of these ways, FoundationOne CDx is available to biopharma companies as an FDA-approved platform for clinical research and as a CGP platform for biopharma companies seeking to develop companion diagnostics for their precision therapeutics.

FoundationOne CDx is available to order online at www.foundationmedicine.com/genomic-testing/order, or visit https://home.foundationmedicine.com/signup to sign up for an account.

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).

Foundation Medicine® is a registered trademark and FoundationOne CDx™ is a trademark of Foundation Medicine, Inc.

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 the ability of FoundationOne CDx to create treatment efficiencies and expand patient access to comprehensive genomic profiling and biomarker-driven medicines; the ability of FoundationOne CDx to improve treatment outcomes; the benefits of FoundationOne CDx to oncologists and patients in the treatment of cancer; and the timing, scope and potential benefits to the oncology community of the commercial launch of FoundationOne CDx. 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 Foundation Medicine is not able to provide FoundationOne CDx for commercial use in the manner or on the timeline currently anticipated by management; and that 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, which is on file with the Securities and Exchange Commission, 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] Jardim DL, Schwaederle M, Wei C, et al. Impact of a Biomarker-Based Strategy on Oncology Drug Development: A Meta-Analysis of Clinical Trials Leading to FDA Approval. *J Natl Cancer Inst*. 2015;15;107(11). doi: 10.1093/jnci/djv253. PMID: 26378224.

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