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Foundation Medicine and Pfizer Announce Broad Partnership to Develop Companion Diagnostics for Pfizer's Oncology Portfolio

-- Foundation Medicine's Data Analytics Platform Will Assist Pfizer in Advancing Discovery and Clinical Development of Novel Oncology Therapies --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced that the company has entered into a broad partnership with Pfizer Inc. (NYSE: PFE). The partnership focuses on development, regulatory support and commercialization of companion diagnostics (CDx) that will be included in updates to FoundationOne CDx™. FoundationOne CDx is Foundation Medicine's FDA-approved comprehensive genomic profiling (CGP) assay for all solid tumors that incorporates multiple companion diagnostics. Pfizer will also benefit from access to FoundationInsights™, Foundation Medicine's data analytics platform, to facilitate novel biomarker discovery and to optimize clinical trial design. The unique combination of FoundationInsights™ and FoundationOne CDx will potentially enable Pfizer to leverage Foundation Medicine's platform technology to accelerate discovery and development of precision oncology therapeutics.

Pfizer currently has 10 FDA-approved oncology medicines that treat a diverse array of solid tumors and hematologic malignancies. In addition, its oncology pipeline includes 17 assets in clinical development and 19 phase 3 studies.

"Our mission to transform cancer care includes partnering with biopharma companies to expedite development of personalized treatment options for patients. We are proud to partner with Pfizer who shares our commitment to precision oncology and biomarker-driven drug development," said Melanie Nallicheri, chief business officer and head of biopharma at Foundation Medicine. "The combination of our FDA-approved comprehensive genomic profiling platform and molecular information solutions, coupled with Pfizer's robust oncology portfolio, enables us to enhance the impact of precision oncology to advance patient care."

FoundationOne CDx assesses all classes of genomic alterations in 324 genes known to drive cancer growth, providing potentially actionable information to help guide treatment decisions. It also reports genomic biomarkers, such as microsatellite instability (MSI) and tumor mutational burden (TMB), that can help inform the use of immunotherapies; genomic alterations in other genes relevant to patient management; and relevant clinical trial information. As such, it is designed to help streamline companion diagnostic development, mitigate risk and advance targeted therapy development. Currently FoundationOne CDx is FDA-approved as a CGP assay for all solid tumors and 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.

Concurrent with FDA approval, the Centers for Medicare & Medicaid Services (CMS) issued a preliminary National Coverage Determination (NCD) for FoundationOne CDx. The draft NCD would provide coverage for FDA-approved companion diagnostic claims, as well as a pathway for additional coverage with evidence development in other solid tumor types. The final policy is expected to issue during the first quarter of 2018 following public comment on the preliminary NCD and an administrative period.

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).

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 Pfizer and Foundation Medicine; the ability of Foundation Medicine products and services, including FoundationOne CDx, to accelerate drug discovery and development; and the timing or scope of any NCD issued by CMS. 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, CMS to issue a final NCD; 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, 2016, filed with the Securities and Exchange Commission on March 2, 2017, 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.

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