August 2, 2016

FoundationOne® Accepted by FDA and CMS for Parallel Review and FDA Expedited Access Pathway

--Parallel Review of FoundationOne, if Successful, Could Result in FDA Approval of the First Pan-Cancer Comprehensive Genomic Profiling Assay Incorporating a Range of Companion Diagnostics, Concurrently with a CMS National Coverage Determination--

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ: FMI) today announced that the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) have accepted FoundationOne for Parallel Review as an innovative technology most likely to benefit from the efficiencies of this program. The FDA also accepted Foundation Medicine's request for review as part of its Expedited Access Pathway (EAP) for breakthrough devices.

If approved, FoundationOne could be the first FDA-approved comprehensive genomic profiling (CGP) assay to incorporate multiple companion diagnostics (CDx) to support precision medicine in oncology, including an indication for use as a companion diagnostic across a diverse range of solid tumors. Importantly, obtaining a Medicare National Coverage Determination (NCD) from CMS concurrently with FDA approval will allow FoundationOne to be offered as a covered benefit under Medicare and avoid the significant time interval and uncertainty that often occurs between FDA approval and an NCD. Based on discussions with FDA and CMS, Foundation Medicine believes the Parallel Review will conclude in the second half of 2017.

"The acceptance of FoundationOne for EAP and Parallel Review is a significant advancement towards the achievement of precision medicine, enhancing patient access to targeted therapies and clinical trials," said Michael Pellini, M.D., chief executive officer of Foundation Medicine. "While we proceed with FDA and CMS, we will continue our work with Palmetto GBA, our Medicare Administrative Contractor (MAC) in North Carolina and a recognized thought leader in molecular diagnostics. We will also continue our work with the MAC in Massachusetts, National Government Services (NGS). Specifically, we will work with Palmetto through its MolDx Program to expand coverage of well-validated CGP assays, such as FoundationOne, to include additional cancer indications beyond the existing local coverage determination (LCD), which currently covers a subset of patients with non-small cell lung cancer (NSCLC). Pursuing avenues at both the local and national levels maximizes the opportunity for Medicare beneficiaries with cancer to have access to FoundationOne."

FoundationOne is a CGP assay for cancer that uniquely detects genomic alterations, including substitutions, insertions and deletions, copy number alterations and select gene rearrangements in 324 genes using DNA isolated from formalin-fixed paraffin-embedded tumor tissue specimens using next-generation sequencing and computational analysis. It is intended that FoundationOne, if approved, will be used to identify patients who may benefit from treatment for solid tumor malignancies in accordance with FDA approval. FoundationOne will also be intended to provide treating physicians with important information, including cancer related variants and molecular signatures to inform molecular eligibility for clinical trials or treatment management according to clinical care guidelines.

Dr. Pellini continued, "Beyond its application in cancer care, an FDA-approved FoundationOne incorporating multiple companion diagnostics would provide a significant and highly differentiated offering for our biopharma partners. We believe this approach, which is designed to expedite approval of additional biomarkers on FoundationOne, both accelerates and de-risks companion diagnostic approval for our biopharma partners seeking a coordinated regulatory strategy for therapeutic drug approval."

Parallel Review provides for concurrent review of medical devices for FDA approval and a national coverage determination by CMS to facilitate patient access to innovative medical devices. The FDA granted Foundation Medicine's request for EAP because it met the three criteria necessary for inclusion in the program, one of which is the large unmet need for comprehensive genomic profiling of tumors. Under the EAP, the FDA works with device sponsors to try to reduce the time and cost from development to an approval decision.

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).

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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 scope and timing of any approval of FoundationOne as a medical device by the FDA and any coverage decision by CMS; any strategies for achieving coverage decisions at the local or national level; changes to the scope of local coverage determinations; FoundationOne's ability to enhance patient access to targeted therapies and clinical trials; and any benefits provided by a FDA-approved version of FoundationOne. 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 FDA does not approve FoundationOne as a medical device or that CMS does not decide to offer FoundationOne as a covered benefit under Medicare; the FDA or CMS is delayed in the completion of its review process; local Medicare administrative contractors decide not to review or revise existing local coverage determinations; FoundationOne does not accelerate the companion diagnostic development and approval process; 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, 2015, which is on file with the Securities and Exchange Commission, as well as other risks detailed in 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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