March 18, 2018

Foundation Medicine Announces Final National Coverage Determination (NCD) from the Centers for Medicare & Medicaid Services (CMS), Including Coverage for FoundationOne CDx™ Across All Solid Tumors

-- Final NCD Significantly Expands Patient Access Beyond the Preliminary NCD --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced that the Centers for Medicare & Medicaid Services (CMS) issued a final National Coverage Determination (NCD) for patients who receive next generation sequencing (NGS) testing with an assay that meets the coverage criteria. Medicare and Medicare Advantage patients who receive testing with FoundationOne CDx™, the first FDA-approved comprehensive genomic profiling (CGP) assay for all solid tumors incorporating a broad set of companion diagnostics, will be eligible for coverage. Below is an outline of key changes made to the final NCD that expand patient access to FoundationOne CDx:

	Preliminary NCD	Final NCD
Patient Eligibility	Coverage for Stage IV metastatic, recurrent cancers	Coverage for Stage III and Stage IV, metastatic, recurrent, relapsed, or refractory cancers
Breadth of Coverage for FoundationOne CDx	Coverage for companion diagnostic claims across five tumor types including non-small cell lung, colorectal, breast, ovarian cancers and melanoma. (Approximately 50% of solid tumors based on Foundation Medicine's volume).	Coverage across all solid tumors
Repeat Testing	No repeat testing included	Repeat testing is covered when a new primary cancer diagnosis is made by the treating physician and the patient meets other clinical criteria
Coverage with Evidence Development (CED)	Included	Removed; Coverage for FoundationOne CDx is for all solid tumors

Based on the final CMS coverage policy, FoundationOne CDx is the first and only NGS assay that presently meets the requirements of the policy, enabling national coverage for all solid tumors. For an NGS diagnostic assay to be covered under the policy, the NGS diagnostic assay must:

- be an FDA approved or FDA 510(k) cleared test with a companion diagnostic claim;
- have a product label from FDA with an indication for use in the patient's cancer; and,
- report results to a treating physician for management of the patient using a report template to specify treatment options.

There are currently no NGS assays that have FDA 510(k) clearance with a companion diagnostic claim.

"We applaud CMS for issuing this final National Coverage Determination that significantly expands coverage beyond the preliminary draft policy. Most notably, the NCD, as it applies to FoundationOne CDx, will provide coverage for eligible patients across all solid tumors," said Troy Cox, chief executive officer at Foundation Medicine. "The final NCD will significantly improve access and coverage for Medicare beneficiaries to comprehensive genomic profiling and biomarker-driven treatments. We look forward to commercializing FoundationOne CDx by the end of March, providing the oncology community with the only FDA-approved broad assay for all solid tumors."

Similar to the coverage available today via local Medicare Administrative Contractors (MACs), the NCD coverage policy will enable NGS assays, including those performed in CLIA-certified laboratories, such as FoundationOne®, FoundationOne® Heme and FoundationACT®, as well as FDA cleared or FDA approved assays without companion diagnostic claims, to

continue to seek local coverage determinations (LCDs) through the MACs.

Please visit CMS.gov to view the final decision memo.

About FoundationOne CDx

FoundationOne CDx is indicated as both (i) a broad companion diagnostic test for approved companion diagnostic claims including, NSCLC, CRC, melanoma, breast and ovarian cancers and (ii) to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. 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. For the complete intended use statement, including companion diagnostic indications, please see the FoundationOne CDx Technical Information, www.foundationmedicine.com/f1cdx.

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 the ability of certain Medicare patients who receive FoundationOne CDx testing to receive Medicare coverage for costs associated with FoundationOne CDx, the ability of the NCD, and FoundationOne CDx as an assay covered under the NCD, to enhance access to comprehensive genomic profiling and biomarker-driven treatments; whether the changes contained in the final NCD as compared to the preliminary NCD will expand the access to reimbursement for certain Medicare beneficiaries; the interpretation of how the NCD will operate and the potential access to Medicare coverage through LCDs from MACs that may exist for certain Foundation Medicine products; the benefits of our products to oncologists and patients in the treatment of cancer and personalized cancer care; and the timing, scope and potential benefits to the oncology community of a 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 the final NCD will not significantly improve access to reimbursement for Medicare beneficiaries; that Foundation Medicine has not correctly interpreted the NCD or that CMS subsequently modifies the NCD; 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.

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