July 17, 2014

Foundation Medicine Receives Approvals from New York State Department of Health for FoundationOne® and FoundationOne Heme®

These Products are the First Fully Informative Genomic Profiles to be Validated by New York State's Regulatory Review Process

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced that it has received final approval from the New York State Department of Health for FoundationOne® and FoundationOne Heme®. These fully informative genomic profiles for solid tumors and hematological malignancies, respectively, have been offered to date under conditional approval to physicians and their patients in the state of New York.

"This approval marks a significant regulatory milestone for Foundation Medicine and serves as a confirmation of the high standard for validation established with FoundationOne and FoundationOne Heme," said Jeffrey Ross, M.D., medical director, Foundation Medicine. "The approval enables New York physicians to utilize our tests, which are designed to identify the molecular growth drivers of each individual's unique cancer, to select relevant targeted therapy options or clinical trials that may be appropriate for their patients."

The state of New York is the only U.S. state that requires an independent regulatory review process, including technical and clinical validation, for laboratory developed tests. FoundationOne and FoundationOne Heme are the only fully informative genomic profiles to be approved by New York State for the detection of all classes of genomic alterations, including base pair substitutions, insertions and deletions, copy number alterations and gene rearrangements, within the full coding region of all genes known to be somatically altered in human cancers. The standard set by New York State represents one of the most rigorous levels of validation required for laboratory developed tests.

About FoundationOne®

FoundationOne, the company's first clinical product, is a fully informative genomic profile for solid tumors used by oncologists to identify the molecular alterations in a patient's tumor and match those alterations with relevant targeted therapies and clinical trials. Using next-generation sequencing in routine cancer specimens, FoundationOne interrogates all genes somatically altered in human cancers that are validated targets for therapy or unambiguous drivers of oncogenesis based on current knowledge. It reveals all classes of genomic alterations including base substitutions, insertions, deletions, copy number alterations and select rearrangements. FoundationOne fits easily into the clinical workflow of the ordering physician, and test results are provided in an easy-to-interpret report supported by a comprehensive review of published literature. FoundationOne is a laboratory-developed test performed at Foundation Medicine's CLIA-certified lab. Please visit www.FoundationOne.com for more information.

About FoundationOne® Heme

FoundationOne Heme is a fully informative genomic profile for hematologic cancers (leukemia, lymphoma and myeloma), sarcomas and pediatric cancers, designed to provide physicians with clinically actionable information to guide treatment options for patients based on the genomic profile of their cancer. It is Foundation Medicine's second clinical product and was developed in collaboration with Memorial Sloan-Kettering Cancer Center. Using next-generation sequencing in routine cancer specimens, FoundationOne Heme interrogates all genes somatically altered in these cancers that are validated targets for therapy or unambiguous drivers of oncogenesis based on current knowledge. The test employs RNA sequencing in addition to DNA sequencing to simultaneously detect all classes of genomic alterations, including base pair substitutions, insertions and deletions, copy number alterations and rearrangements, and gene fusions (a type of alteration that is a common driver of hematologic malignancies, sarcomas and pediatric cancers). FoundationOne Heme fits easily into the clinical workflow of the ordering physician, and test results are provided in an easy-to-interpret report supported by a comprehensive review of published literature. FoundationOne Heme is a laboratory-developed test performed at Foundation Medicine's CLIA-certified lab. Please visit www.FoundationOne.com for more information.

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's clinical assays, FoundationOne for solid tumors and FoundationOne Heme for hematologic malignancies, sarcomas

and pediatric cancers, provide a fully informative genomic profile to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies 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 www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

Cautionary Note Regarding Forward-Looking Statements

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 New York state physicians to continue to utilize FoundationOne and FoundationOne Heme. 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 risk that the New York State Department of Health will not continue to approve the offering of FoundationOne and FoundationOne Heme to physicians in the State of New York; 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, 2013, 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.

Pure Communications, Inc.
Media Contact:
Dan Budwick, 973-271-6085
dan@purecommunicationsinc.com
or
Investor Contact:
Khaled Habayeb, 617-418-2283
ir@foundationmedicine.com

Source: Foundation Medicine, Inc.

News Provided by Acquire Media