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Foundation Medicine Adds New Immunotherapy Features to Its Market-Leading Products

-- First Fully-Integrated and Validated Assessments of Tumor Mutational Burden (TMB) and Microsatellite Instability (MSI) Provide Oncologists with a Single Testing Solution to Guide Personalized Immunotherapy-based Treatment Plans --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Foundation Medicine, Inc.](http://www.foundationmedicine.com) (NASDAQ:FMI) today announced the addition of new clinical markers to its FoundationOne® and FoundationOne® Heme products, which are designed to enhance oncologists' insight into potential response to immunotherapies. This ability to determine TMB and MSI from its assays is additional to the existing comprehensive profiling of genes provided by FoundationOne and FoundationOne Heme. Taken together, the molecular information provided by Foundation Medicine provides unique insights to physicians and enhances their ability to predict response to immunotherapies, identify targeted therapeutic options, and improve access to clinical trials all from a single assay.

"Cancer immunotherapies are at the forefront of cancer treatment, and new, quantitative approaches are needed to predict clinical responses to this important, but also expensive, class of therapies," said Vincent Miller, M.D., chief medical officer of Foundation Medicine. "Prior to our ability to measure TMB and MSI with FoundationOne, these biomarkers could only be detected separately, either through tests such as immunohistochemistry, polymerase chain reaction (PCR) or whole exome sequencing. Importantly, high-quality, predictive TMB scoring can only be accurately performed with sophisticated algorithms developed to work with broad, hybrid capture-based platforms that can analyze all relevant alterations simultaneously. Integrating this capability to measure TMB and MSI with one tissue sample, and reported in one test, represents an important advance in clinical care."

A growing body of evidence, most recently [presented](#) at the American Society of Clinical Oncology (ASCO) annual meeting this year, validates the ability of a new independent marker, TMB, to predict the likelihood of response to cancer immunotherapies. TMB is reported as the total number of DNA mutations per megabase in a tumor sequence. This phenomenon has been validated across a wide range of tumor types, including advanced bladder cancer, lung cancer, breast cancer, colorectal cancer, advanced head and neck cancer and melanoma. Some tumors develop high TMB as a result of defective mismatch repair of DNA, a condition in which the length of certain DNA areas becomes more widely varied than normal. This condition, which is referred to as MSI-high and MSI-high tumors, almost always has a high TMB.

"The ability to accurately measure multiple biomarkers simultaneously, including TMB and MSI, is an important advance for the field of cancer immunotherapy, and one that is unique to Foundation Medicine," said Thomas George, M.D., GI oncology program director, University of Florida. "Foundation Medicine's combination of advanced sequencing platforms and highly-specific algorithms gives me access to all relevant genomic biomarkers for my patients at once, helping to save both time and tissue."

"We were encouraged by the findings presented at ASCO, including the possibility of identifying patients more likely to benefit from checkpoint inhibitor immunotherapy," said Dr. Miller. "Our goal is to empower doctors and patients with a full range of relevant, actionable genomic information, and we're excited to offer our distinctive solution to estimate TMB and MSI simultaneously and with exceptional accuracy, supported by sophisticated algorithms and rooted in contextual insights from our knowledgebase FoundationCORE™. This is something no other next-generation sequencing platform offers."

Independent of the FoundationOne and FoundationOne Heme assays, Foundation Medicine also offers testing for PD-1 and PD-L1 protein expression, providing, in combination with the FoundationOne assays, a full suite of cancer immunotherapy assays for oncologists.

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 ability of FoundationOne and FoundationOne Heme to identify and predict the likelihood of response to immunotherapies, and the ability of FoundationOne and FoundationOne Heme to inform therapeutic choices in cancer, including leading to physician-directed therapy changes and to improve patient outcomes. 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 company's TMB and MSI analysis do not perform as expected or the results thereof are not widely accepted; subsequent research renders TMB and/or MSI status less useful or not useful in clinical practice; physicians may not be able to obtain access to relevant targeted therapies, immunotherapies or clinical trials matched to molecular findings identified by FoundationOne or FoundationOne Heme as readily as expected; 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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