



December 7, 2013

## Foundation Medicine Launches FoundationOne™ Heme, Developed in Collaboration with Memorial Sloan-Kettering Cancer Center

*FoundationOne Heme, Foundation Medicine's Second Clinical Product, is a Fully Informative Genomic Profile for Hematologic Malignancies, Sarcomas and Pediatric Cancers*

CAMBRIDGE, Mass. & NEW YORK--(BUSINESS WIRE)-- [Foundation Medicine](#) announced today the launch of its second clinical product, FoundationOne™ Heme, a fully informative genomic profile for hematologic cancers (leukemia, lymphoma and myeloma), as well as many sarcomas and pediatric cancers. The test has been developed in collaboration with [Memorial Sloan-Kettering Cancer Center](#), and is designed to provide physicians with clinically actionable<sup>1</sup> information to guide treatment options for patients based on the genomic profile of their cancer.

"By introducing our second clinical product, FoundationOne Heme, in only our second year of commercialization, we are demonstrating our commitment to ongoing product innovation to make molecular information broadly available to the hematology and oncology communities at academic medical centers and community hospitals worldwide," said Michael J. Pellini, M.D., president and chief executive officer of Foundation Medicine. "Consistent with FoundationOne, our first clinical product for solid tumors, this new test is designed to fit within routine clinical practice and provide a physician with all of the relevant genomic information needed to make an informed treatment decision, which may include a targeted therapy or clinical trial. Our shared goal in developing FoundationOne Heme with Memorial-Sloan Kettering is to enable precision medicine and to advance treatment options for more patients living with cancer."

FoundationOne Heme uses comprehensive, clinical next-generation sequencing (NGS) to assess routine cancer specimens for all genes that are currently known to be somatically altered and unambiguous drivers of oncogenesis in hematologic malignancies, as well as many sarcomas and pediatric cancers. Utilizing NGS, FoundationOne Heme simultaneously detects all classes of genomic alterations, including base pair substitutions, insertions and deletions, copy number alterations and select gene rearrangements in 405 cancer-related genes. In addition to DNA sequencing, FoundationOne Heme employs RNA sequencing across 265 genes to capture a broad range of gene fusions, a type of alteration that is a common driver of hematologic cancers, 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.

"Our vision is to make cancer genomic testing available in routine care to enable more precise and informed treatment decisions for patients with a broad range of cancers," added Craig B. Thompson, M.D., president and chief executive officer of Memorial Sloan-Kettering Cancer Center. "We look forward to continuing our efforts with Foundation Medicine to advance the ongoing development of this best-in-class test and to further define its clinical utility in patients with hematologic cancers."

[New data from ten studies](#) demonstrating the utility of FoundationOne Heme in hematologic malignancies will be presented during the 2013 American Society of Hematology Annual Meeting taking place December 7-10 in New Orleans. FoundationOne Heme was developed using technology, methods and computational algorithms developed by Foundation Medicine, combined with Memorial Sloan-Kettering's deep and vast expertise in clinical and laboratory research into hematologic malignancies. Over the seven-month development process, researchers from Memorial Sloan-Kettering analyzed more than 400 patient samples to demonstrate the accuracy and performance of FoundationOne Heme in validation studies. Data demonstrating that comprehensive genomic profiling with FoundationOne Heme may expand treatment options for patients will be presented in an oral presentation by Ross L. Levine, M.D., medical oncologist and member of the Human Oncology and Pathogenesis Program at Memorial Sloan-Kettering, on Monday, December 9, 2013 (titled *Identification Of Actionable Genomic Alterations In Hematologic Malignancies By a Clinical Next Generation Sequencing-Based Assay*, abstract number 230). Foundation Medicine will commercialize FoundationOne Heme in the United States and internationally. For more information or to order FoundationOne Heme, please visit [www.FoundationOne.com](http://www.FoundationOne.com).

### About FoundationOne™ Heme

FoundationOne Heme is a fully informative genomic profile for hematologic cancers (leukemia, lymphoma and myeloma), as well as many 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 commercially available targeted sequencing assay 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](http://www.FoundationOne.com) for more information.

## About Memorial Sloan-Kettering Cancer Center

[Memorial Sloan-Kettering Cancer Center](http://www.MemorialSloanKettering.org) is the world's oldest and largest private cancer center with more than 125 years devoted to exceptional patient care, innovative research, and outstanding educational programs. Memorial Sloan-Kettering is one of 41 National Cancer Institute—designated Comprehensive Cancer Centers, with state-of-the-art science flourishing side by side with clinical studies and treatment.

The close collaboration between physicians and scientists enables Memorial Sloan-Kettering to provide patients with the best care available as they work to discover more-effective strategies to prevent, control, and ultimately cure cancer in the future. Memorial Sloan-Kettering's education programs train future physicians and scientists, and the knowledge and experience they gain at Memorial Sloan-Kettering has an impact on cancer treatment and biomedical research around the world.

## About Foundation Medicine

[Foundation Medicine](http://www.FoundationMedicine.com)<sup>®</sup> (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](http://www.FoundationOne.com)<sup>™</sup> for solid tumors and [FoundationOne](http://www.FoundationOne.com)<sup>™</sup> Heme for hematologic malignancies, each provide a fully informative genomic profile to identify a patient's individual molecular alterations 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](http://www.FoundationMedicine.com) or follow Foundation Medicine on [Twitter](https://twitter.com/FoundationATCG) (@FoundationATCG).

*Foundation Medicine<sup>®</sup> is a registered trademark, and FoundationOne<sup>™</sup> is a trademark, of Foundation Medicine, Inc.*

## Cautionary Notes 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 commercial launch of FoundationOne<sup>™</sup> Heme, the design, development and commercialization of FoundationOne Heme, the ease of use of FoundationOne Heme in routine clinical practice, the delivery of relevant genomic information in the FoundationOne Heme report, the benefits to patients with hematologic cancers of next-generation sequencing, and the release of data and studies related to the utility of 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 risks that FoundationOne Heme may not meet the clinical standards expected for the test, or may not achieve significant commercial adoption or reimbursement support; that Foundation Medicine may be unable to achieve profitability, to compete successfully, to manage its growth, or to develop its molecular information platform; and the risks described under the caption "Risk Factors" in Foundation Medicine's Form 10-Q, 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.*

1. Alterations are defined as clinically actionable if linked to an FDA approved targeted therapy in the tumor under study or to another tumor type, or to an open clinical trial targeting a relevant pathway.

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