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# Foundation Medicine and Memorial Sloan Kettering Publish Validation Data for FoundationOne® Heme in the Journal Blood

*New Data Demonstrate Accuracy and Clinical Application of Comprehensive Genomic Profiling to Improve the Diagnosis and Treatment of a Wide Range of Hematologic Malignancies*

CAMBRIDGE, Mass. & NEW YORK--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) and Memorial Sloan Kettering Cancer Center (MSK) today announced the publication of new, seminal data validating FoundationOne® Heme - the fully informative comprehensive genomic profiling assay for hematologic malignancies developed as part of their collaboration - further supporting its integration into oncology clinical practice. The data, available online as a first edition and soon to be published in an upcoming issue of the journal *Blood,* demonstrate that FoundationOne Heme has proven highly accurate in detecting the types of genomic alterations known to impact diagnosis, therapy selection and prognosis in hematologic cancers. Importantly, the publication demonstrates the molecular information gleaned from comprehensive genomic profiling can be utilized to accurately match patients with an appropriate therapeutic approach.

"Foundation Medicine has an established track record of developing genomic profiling assays with the highest standards of analytical and clinical validation," said Vincent Miller, M.D., chief medical officer, Foundation Medicine. "Publication of our validation data in this highly regarded, peer-reviewed journal supports the clinical significance of the FoundationOne Heme assay, in particular, for its ability to identify specific therapeutic targets, to help refine underlying diagnosis, and to improve prognostic and risk stratification of hematologic cancers."

"The development of FoundationOne Heme represents a state-of-the-art genomics assay which can be used to profile patients with hematologic malignancies worldwide, which is a critical step in improving outcomes for all patients," stated Ross Levine, M.D., a physician-scientist and the Laurence Joseph Dineen chair in leukemia research at MSK. "Our team's expertise in hematologic malignancies and in translating genomics to the clinic has allowed us to partner with Foundation Medicine to bring this innovative genomic test to the patients we treat."

Conventional diagnostic assays, including FISH and real-time PCR, are designed to identify a sub-set of genomic alterations, and in some cases, there are no assays that can reliably identify specific rearrangements. FoundationOne Heme, an integrated DNA/RNA platform using targeted hybrid-capture next-generation sequencing, is a proven and effective comprehensive genomic profile developed to detect all types of genomic alterations with therapeutic relevance, including single-nucleotide substitutions, insertions and deletions, copy number alterations and rearrangements, which are not fully evaluated using conventional diagnostic assays.

MSK and Foundation Medicine collaborated to develop FoundationOne Heme, which was commercially launched in 2013. The assay is performed using archived FFPE, blood or bone marrow samples with high accuracy in a clinically relevant timeframe in Foundation Medicine's laboratory, which is certified by New York State and CLIA and is CAP accredited. FoundationOne Heme simultaneously detects all classes of genomic alterations in the DNA of 405 cancer-related genes and 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. It is designed to provide physicians with clinically actionable information to guide treatment options for patients based on the genomic profile of their cancer.

**Key Study Findings**

- Established analytic accuracy of detecting substitutions, insertions and deletions (indels) and copy number alterations (CNAs) by comparing the performance of the new assay with Foundation Medicine's DNA-only assay that has previously undergone comprehensive validation across a large number of clinical samples. Compared to FoundationOne, FoundationOne Heme contains an additional 90 genes relevant to hematologic malignancies.
  - Samples that were previously profiled with a validated test in which 169 alterations were identified in 55 genes common to both assays. The concordance between the two sets of results was 99.4%.
- Blinded comparisons were performed with CLIA-certified diagnostic assays, including Sequenom, RT-PCR, FISH and PCR fragment analysis, for 76 clinical specimens previously tested for 214 clinical relevant alterations in 11 genes that are known and routinely tested in clinical practice in AML, ALL and MDS.
  - Overall concordance was 99% (211/214).
  - In addition to the concordance analysis, genomic profiling of the 76 test samples identified 126 additional

somatic alterations which are not covered by available hot spot assays in the given disease type, including clinically relevant genomic alterations in *KRAS, TET2, EZH2*, and *DNMT3A.*

- In independent low frequency variants ( < 10% mutant allele frequency), 20 of 21 variants were confirmed from AmpliSeq assay and another hotspot clinical assay.

- Combined DNA and RNA sequencing approach accurately detects a wide variety of genomic rearrangements and gene fusions with immediate clinical value in hematologic malignancies.
  - Sensitivity for fusion detection at 20% or greater tumor fraction was 100% (161/161) and 98% (84/86) at 10% tumor fraction.
- Clinical experiences from 3,696 hematologic malignancies are summarized, with a high fraction of clinically relevant genomic alteration detected.
  - At least one driver alteration was identified in 95% tumor specimens, and 77% cases harbored at least one alteration linked to a commercially available targeted therapy or one that is in clinical development. In addition, 61% of cases harbored at least one alteration with known prognostic relevance in that tumor type.
  - Genomic rearrangements were detected from 37% of clinical hematologic malignancies; known and novel fusions in kinase drug targets are highlighted.
  - In 16 cases of high-risk, BCR-ABL-negative B-ALL malignancies, known and novel clinical relevant genomic alterations were detected by FoundationOne Heme, and gene fusions involving *JAK2, CRLF2 and EPOR* were detected in 9 of 16 cases.

**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 http://www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

**About Memorial Sloan Kettering**

We are the world's oldest and largest private cancer center, home to more than 14,000 physicians, scientists, nurses, and staff united by a relentless dedication to conquering cancer. As an independent institution, we combine 130 years of research and clinical leadership with the freedom to provide highly individualized, exceptional care to each patient. And our always-evolving educational programs continue to train new leaders in the field, here and around the world. For more information, go to www.mskcc.org.



**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 performance of FoundationOne Heme; the ability of comprehensive genomic profiling, including FoundationOne Heme, to match patients with therapeutic treatments; and the integration of FoundationOne Heme into clinical practice. 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 does not perform in the same manner as the published data 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 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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