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FoundationOne™ Heme Enables Identification of Genomic Alterations Not Identified By Conventional Methods Across Hematologic Malignancies

Comprehensive Genomic Profiling Utilizing DNA and RNA Sequencing May Expand Treatment Options For Patients; Data Presented at American Society of Hematology Annual Meeting

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine today announced new data demonstrating that its fully informative genomic profile for hematologic cancers, FoundationOne™ Heme, can be performed in routine clinical cancer specimens to identify all classes of genomic alterations, including gene fusions, across hundreds of genes related to oncogenesis in patients with hematologic malignancies. These data were presented today in an oral presentation titled *Identification Of Actionable Genomic Alterations In Hematologic Malignancies By a Clinical Next Generation Sequencing-Based Assay* (abstract number 230) by Ross L. Levine, M.D., hematologist/oncologist and associate member, Human Oncology and Pathogenesis Program and Leukemia Service, Memorial Sloan-Kettering Cancer Center, at the American Society of Hematology Annual Meeting in New Orleans.

"These data demonstrate the feasibility of comprehensive genomic profiling in patients with hematologic malignancies, and represent a significant step forward in making this approach available in routine clinical care," said Dr. Levine. "FoundationOne Heme enables the identification of genomic alterations that are molecular drivers of each patient's cancer which may help to expand and inform treatment options for individual patients, advance the development of new therapies against these targets, and ultimately improve patient outcomes."

In this study, Memorial-Sloan Kettering and Foundation Medicine researchers used FoundationOne Heme to analyze routine cancer specimens from 319 patients with a range of hematologic malignancies, including leukemia, lymphoma and myeloma. DNA and RNA were successfully extracted from 96% (350/362) of specimens. Ninety-one percent of samples (317/350) contained sufficient tumor content for analysis, and a total of 885 alterations were identified (3.1 average alterations per sample). The most frequent alterations across all hematologic malignancies included: *TP53*; *ASXL1*; *KRAS*; *NRAS*; *IDH2*; *TET2*; *SF3B1*; *JAK2*; *MLL2*; *DNMT3A*; *RUNX1*; *SRSF2*; *FLT3* internal tandem duplication; *MLL* partial tandem duplication; homozygous loss of *CDKN2A/B;* and focal amplification of *REL*. RNA sequencing enabled detection of gene fusions in *BCL2/6*, *MYC*, *MLL*, *MLL2*, *NOTCH2*, *ABL1* and *ETV6* demonstrating the ability of FoundationOne Heme to reliably detect this type of alteration that is a common driver of hematologic malignancies.

Notably, the high accuracy of FoundationOne Heme enabled detection of clinically actionable[1] genomic alterations that were not detected using standard clinical assays, including:

- *IDH1/2* alterations in a spectrum of myeloid/lymphoid malignancies;
- Recurrent *BRAF* alterations in refractory CLL (chronic lymphocytic leukemia) and myeloma;
- Alterations in the JAK-STAT signaling pathway in diffuse-large B cell lymphoma.

"Cancer care is being transformed by the ability to perform comprehensive genomic analysis of an individual's tumor, and then using this molecular information to identify the most relevant targeted therapies or clinical trials for each patient based on their genomic profile," said Vincent Miller, M.D., chief medical officer, Foundation Medicine. "We continue to demonstrate the increasing value of comprehensive genomic profiling in solid tumors, and we are now very pleased to report these initial data showing the utility of this approach in hematologic cancers. We believe FoundationOne Heme will help advance patient care and enable precision medicine for patients with a range of hematologic malignancies."

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 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, 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 or follow Foundation Medicine on Twitter (@FoundationATCG).

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 benefits to patients with hematologic cancers of next-generation sequencing, the ability of FoundationOne™ Heme to identify actionable alterations relevant to hematologic cancers, the feasibility and utility of FoundationOne Heme for use in routine clinical practice, and the release of data from a clinical study demonstrating the value FoundationOne Heme in the treatment of hematologic cancers. All such forward-looking statements are based on 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; FoundationOne Heme may not be suitable for use in routine clinical practice; FoundationOne Heme may not have value in the treatment hematologic cancers; and FoundationOne Heme may not be readily available for clinical use as a result of FoundationOne Heme not achieving significant commercial adoption or reimbursement support or Foundation Medicine not achieving profitability, competing successfully, managing its growth, developing its molecular information platform, or not addressing other 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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