

December 10, 2013

## Novel And Previously Reported Genomic Alterations Identified in Clinical Multiple Myeloma Cases Using FoundationOne™ Heme

*Comprehensive Genomic Profiling May Lead To New Therapeutic Options For Patients; Data Presented at American Society of Hematology Annual Meeting*

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Foundation Medicine](#) today announced new data from a pilot study demonstrating that its fully informative genomic profile for hematologic malignancies, FoundationOne™ Heme, identified both novel and previously reported clinically actionable<sup>1</sup> genomic alterations in multiple myeloma cases. These data were presented in an oral presentation titled *Pilot Study To Evaluate The Prevalence Of Actionable Oncogenic Mutations In Patients With Relapsed Refractory Multiple Myeloma* (abstract number 755) by Alexander Lesokhin, M.D., medical oncologist, Memorial Sloan-Kettering Cancer Center, at the 55<sup>th</sup> American Society of Hematology Annual Meeting in New Orleans.

"Multiple myeloma is a treatable, but ultimately incurable, blood cancer that eventually becomes resistant to all currently available therapies," said Dr. Lesokhin. "Advances in clinical next-generation sequencing have made it possible to rapidly identify genomic alterations that may be driving a patient's cancer and could inform treatment options leading to advances in clinical development of new targeted therapies in multiple myeloma patients."

In this study, researchers at Memorial Sloan-Kettering used FoundationOne Heme to analyze whole bone marrow aspirate samples from 28 newly diagnosed and 27 heavily pre-treated multiple myeloma patients. High coverage and high quality sequence data was obtained in 98% (54/55) of cases, and alteration prevalence was examined in 63% of (35/55) samples with sufficient plasma cell content. In the analysis:

- A high frequency of alterations in the MAPK pathway was observed, including mutually exclusive alterations in *NRAS* and *KRAS* in 48% of cases, and *BRAF* V600E alteration in 3% of cases.
- Fourteen percent of cases had *TET2* frameshift/nonsense alterations or *IDH2* alterations, suggesting the DNA hydroxymethylation pathway is targeted by recurrent somatic alterations in multiple myeloma.
- Alterations in epigenetic modifiers were identified in 41% of cases, including alterations in *TET2/IDH*, chromatin modifying enzymes/scaffolds (*ARID1A*, *ASXL1*) and DNA methyltransferases (*DNMT3A*).
- Novel alterations in DNA repair pathways (*ATM*, *FANCA*, *FANCD2*) and in *FAT3* were identified, suggesting there are novel disease alleles which require functional investigation for their role in multiple myeloma pathogenesis.

"These data support the clinical utility of FoundationOne Heme and the benefit of our comprehensive genomic profiling approach in identifying oncogenic drivers in multiple myeloma," said Vincent Miller, M.D., chief medical officer, Foundation Medicine. "*MEK/RAF* inhibition has demonstrated clinical efficacy in a range of cancers and there are emerging data that epigenetic and targeted therapies may provide benefit in patients with *TET2/IDH* mutations. Therefore, these results demonstrate that FoundationOne Heme can identify clinically actionable alterations that may support the clinical development of new treatment options and advance precision medicine for multiple myeloma patients."

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

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### **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 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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Source: Foundation Medicine

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