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Foundation Medicine Identifies Actionable Genomic Alterations in Pediatric Cancers; New Clinical Data to be Presented at 2014 ASCO Annual Meeting

Data Demonstrate Accurate Genomic Profiling May Inform Targeted Therapeutic Options for Pediatric Patients with Cancer; FoundationOne® Heme Now Available for Profiling Cancer in Children

CAMBRIDGE, Mass. & CHICAGO--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ: FMI) today announced new data demonstrating that FoundationOne® identified actionable genomic alterations in a broad range of pediatric cancers. These data will be presented today in a poster highlights presentation at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting, abstract number 10035[1].

"Oncology is undergoing a paradigm shift with the increasingly successful utilization of targeted therapies, but unfortunately, there are limited approved targeted therapeutic options for pediatric patients with cancer, and genomic profiling has yet to be broadly applied in this patient population," said Nancy Goodman, Founder and Executive Director, Kids v Cancer. "These data demonstrate that informative genomic profiling across a broad range of pediatric solid tumor clinical samples identifies actionable alterations in the majority of samples profiled. This approach has the potential to inform new therapeutic options that may not have otherwise been considered for pediatric patients."

Fully informative genomic profiling was conducted using FoundationOne on 400 pediatric tumors from patients 21 years old or younger at the time of sample procurement. The pediatric clinical experience consisted of: neuroblastoma (n=104), soft tissue (n=77), brain (n=56), leukemia (n=34), bone (n=25), other (n=20), liver (n=16), kidney (n=15), unknown (n=14), ovary (n=12), lung (n=12), lymphoma (n=6), colon (n=5) and head or neck (n=4). Genomic alterations were identified in a majority of 326 unselected pediatric cancer clinical cases, and 241 of these patients were found to have at least one alteration targeted by an approved therapy or investigational therapy in clinical trials. These results suggest that routine use of accurate, comprehensive genomic profiling with FoundationOne or FoundationOne® Heme in pediatric patients may inform treatment options.

"The unique physical nature of children poses special complexities and challenges in treating their disease not always present in adults with similar diagnoses. We believe the adoption of fully informative genomic profiling into the routine care of these young patients will help to guide therapeutic options in many cases and ultimately improve patient outcomes," said Vincent Miller, M.D., chief medical officer of Foundation Medicine and co-author of the study. "Since this study was conducted, Foundation Medicine has launched a second clinical product, FoundationOne Heme, that more fully characterizes gene fusions, a class of genomic alteration that is a common driver of pediatric cancers. By revealing potential treatment options based on the genomic alterations driving each patient's disease, we are identifying previously unconsidered therapeutic options and informing potential future treatments that may improve pediatric cancer care."

About FoundationOne®

FoundationOne, the company's first clinical product, is a fully informative genomic profile for solid tumors used by oncologists to identify the molecular alterations in a patient's tumor and match those alterations with relevant targeted therapies and clinical trials. Using next-generation sequencing in routine cancer specimens, FoundationOne interrogates all genes somatically altered in human cancers that are validated targets for therapy or unambiguous drivers of oncogenesis based on current knowledge. It reveals all classes of genomic alterations including base substitutions, insertions, deletions, copy number alterations and select rearrangements. FoundationOne 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 is a laboratory-developed test performed at Foundation Medicine's CLIA-certified lab. Please visit www.FoundationOne.com for more information.

About FoundationOne® Heme

FoundationOne Heme is a fully informative genomic profile for hematologic cancers (leukemia, lymphoma and myeloma), 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 clinical product 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, 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 www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

Cautionary Note 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 of next-generation sequencing of their tumors, the utility of FoundationOne in informing treatment of certain patient populations, and clinical data related to FoundationOne. 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 Foundation Medicine's products will not be able to identify genomic alterations in the same manner as prior clinical 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, 2013, 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. Hawryluk, M. et al, "Clinical application of comprehensive next-generation sequencing-based genomic profiling identified actionable genomic alterations in pediatric solid tumors and hematolymphoid malignancies: the Foundation Medicine pediatric experience." 2014 American Society of Clinical Oncology (ASCO) Annual Meeting, abstract number 10035.

Pure Communications, Inc.
Media Contact:
Dan Budwick, 973-271-6085
dan@purecommunicationsinc.com
or
Foundation Medicine, Inc.
Investor Contact:
Matt Clawson, 617-418-2283
ir@foundationmedicine.com

Source: Foundation Medicine, Inc.

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