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Foundation Medicine Announces Publication of Analytic Validation Study of FoundationOne™ in Nature Biotechnology

Publication Establishes Standard of Analytic Performance for Clinical Application of Next-Generation Sequencing in Cancer

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ: FMI) today announced that results from a 24-month, multi-institution collaboration demonstrating the analytic validation of its cancer genomic profiling assay, FoundationOne™, were published in the current online edition of *Nature Biotechnology.*[1] FoundationOne is a comprehensive, next-generation sequencing (NGS) based test used to characterize all classes of molecular alterations (base substitutions, short insertions and deletions ('indels'), copy number alterations and select rearrangements) across 287 cancer-related genes from routine formalin-fixed, paraffin-embedded (FFPE) clinical specimens. The publication also describes clinical application of this assay across 2,221 consecutive patient cases.

Comprehensive genomic testing is becoming critical to deliver the most effective care for patients with cancer. However, analytic validation of NGS-based tests presents a challenge to clinical application due to the fact that thousands of potential variants may be detected, and most have no gold standard with which to compare. This publication is the first to apply and extend the guidelines established by the Next-Generation Sequencing: Standardization of Clinical Testing (Nex-StoCT) workgroup[2] to validate a clinical sequencing-based assay for cancer, therefore setting the standard for validation of targeted NGS in cancer.

"Clinical cancer care is undergoing a fundamental shift toward treating patients based on the specific molecular drivers of their disease, and a sequencing-based diagnostic assay that comprehensively and accurately characterizes the genomic alterations occurring within an individual's tumor is essential for the implementation of this therapeutic strategy," stated Lajos Pusztai, M.D., co-director of the Cancer Genetics and Genomics Research Program at Yale Cancer Center and co-author of the study. "This study is instrumental in establishing the technical validity of next-generation sequencing in the clinic and enables the practice of precision medicine wherein the molecular characterization of a patient's tumor informs the patient's individual treatment."

Foundation Medicine assessed the accuracy and precision of FoundationOne using reference samples of pooled cell lines and hundreds of clinical cancer specimens with diagnostic testing results generated by established clinical assays. FoundationOne was found to be highly accurate in identifying genomic alterations, including sensitivity greater than 99% for detection of base substitutions, 98% for detection of insertions and deletions, and greater than 95% for detection of copy number alterations, while maintaining greater than 99% specificity. Application of FoundationOne to 2,221 clinical cases revealed clinically actionable alterations in 76% of tumor samples, three times the number of actionable alterations detected by other currently available diagnostic tests. Alterations are defined as clinically actionable if linked to an FDA approved targeted therapy in the tumor under study or another solid tumor, a known or suspected contraindication to a given therapy, or an open clinical trial for which the alteration confers patient eligibility.

"FoundationOne was proven to have the sensitivity and specificity required for routine clinical practice, and it identified more than three times the clinically actionable alterations that are identifiable using a collection of six commercially available and commonly used diagnostic tests, including the other most common NGS-based tests. This comprehensive approach directly translates into more treatment options for patients," said Michael J. Pellini, M.D., president and chief executive officer of Foundation Medicine. "We believe this study establishes the standard for analytic performance that is required for patients with cancer to benefit from the clinical application of next-generation sequencing of their tumors."

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 initial clinical assay, FoundationOne™, is 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 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 shift in clinical cancer care towards precision medicine, the benefits to patients of next-generation sequencing of their tumors, and the adoption of FoundationOne™ into routine clinical oncology practice and clinical trials. 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™ and any subsequent products may never achieve significant commercial adoption or reimbursement support; Foundation Medicine is 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 Registration Statement on Form S-1 (File No. 333-190226), 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. Frampton, G.M. et al. Validation and clinical application of a cancer genomic profiling test using next-generation sequencing. *Nature Biotechnology*, 2013; DOI: 10.1038/NBT.2696.

2. Gargis, A.S. et al. Assuring the quality of next-generation sequencing in clinical laboratory practice. *Nature Biotechnology* **30**, 1033-1036 (2012).

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