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Foundation Medicine Identifies Novel, Clinically Actionable Gene Fusion NTRK1 in Lung Cancer; Data Published in Nature Medicine

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced that the discovery of a novel and potentially clinically actionable oncogenic gene fusion in lung cancer, *NTRK1*, using FoundationOne™, was published in the current online edition of *Nature Medicine*[1]. Lung cancer remains the leading cause of cancer-related death in men and women in the United States[2]; however, the use of targeted therapies in lung cancer has led to significant clinical benefit for patients with *EGFR* mutations and *ALK* fusions. Therefore, the identification of new, drug-sensitive oncogenes in this disease is of great clinical interest and has the potential to expand treatment options for patients.

"Our understanding of cancer complexity is increasing, and lung cancer continues to be dissected into a series of uncommon or even rare diseases based on the molecular alterations driving a patient's individual cancer," stated Vincent Miller, M.D., chief medical officer at Foundation Medicine and co-author of the study. "By discovering a new and potentially clinically actionable gene fusion in lung cancer, we believe this is an opportunity to explore new and different treatment options for patients harboring this fusion. Based on these findings, we believe clinical studies of selective TRK inhibitors in *NTRK1* rearranged non-small cell lung cancer are warranted."

Michael J. Pellini, M.D., president and chief executive officer at Foundation Medicine added, "In addition to making important contributions to cancer patient care, the discovery of novel gene markers using FoundationOne is an excellent example of how clinical and commercial progress can coincide, especially in collaboration with academic investigators. These discoveries drive the evolution of FoundationOne, support new and ongoing collaborations with our pharma partners, and provide further evidence that our comprehensive approach yields high clinical utility."

In an effort to identify additional potential oncogenes in lung cancer, Foundation Medicine and its collaborators, the University of Colorado Cancer Center and Dana-Farber Cancer Institute, used FoundationOne to assess cancer-related genes on tumor samples from 36 patients negative for activating alterations in *EGFR*, *KRAS*, *ALK*, and *ROS1* using standard clinical assays. Researchers identified novel gene fusions harboring the kinase domain of the *NTRK1* gene that encodes the TRKA receptor. Both the *MPRIP-NTRK1* and *CD74-NTRK1* fusions demonstrated constitutive TRKA kinase activity. Preclinical data show that treatment of cells expressing *NTRK1* fusions with inhibitors of TRKA kinase activity (ARRY-470, CEP-701, and crizotinib) inhibited tumor growth. In the study, one patient harboring the *MPRIP-NTRK1* fusion demonstrated a minor radiographic response to crizotinib. Three of 91 patients (3.3%) without known oncogenic alterations profiled by FoundationOne harbored an *NTRK1* gene fusion. These results suggest that *NTRK1* gene fusions are a new oncogenic alteration in lung cancer and TRK inhibitors should be evaluated in clinical trials in patients harboring this gene fusion.

"Following the recent publication of our analytic validation study of FoundationOne, the identification of *NTRK1* further supports the clinical utility of comprehensive next-generation sequencing as a method to discover novel drug sensitive genomic alterations that would not otherwise be tested for or identified using currently available diagnostic approaches," commented Phil Stephens, Ph.D., vice president, cancer genomics at Foundation Medicine. "Additionally, the preclinical data and preliminary clinical data on patient response to TRK inhibitor therapy informed by FoundationOne are very encouraging for further clinical investigation of TRK inhibitors in this patient population."

Foundation Medicine last week 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 online edition of *Nature Biotechnology*[3]. This publication is the first to apply and extend the guidelines established by the Next-Generation Sequencing: Standardization of Clinical Testing (Nex-StoCT) workgroup to validate a clinical sequencing-based assay for cancer, therefore setting the standard for validation of targeted NGS in cancer.

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 new and potentially clinically actionable gene fusions, the development of new treatment options for patients with certain gene fusions, the evolution of FoundationOne™, and the clinical utility of FoundationOne™ and next-generation sequencing as a method to discover novel drug sensitive genomic alterations. 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. Vaishnavi, A. et al. Oncogenic and drug sensitive NTRK1 rearrangements in lung cancer. *Nature Medicine,* 2013. DOI: 10.1038/nm.3352.

2. American Cancer Society. *Cancer Facts & Figures 2012*.

3. 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.

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