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New Data with FoundationOne® Supports Clinical Utility and Improved Outcomes from Molecularly Matching Non-Small Cell Lung Cancer Patients to Targeted Therapy

Data Published in Peer-Reviewed Journals Provide Further Evidence of the Ability of Comprehensive Genomic Profiling to Find Clinically Relevant Alterations Often Missed by Hotspot Assays

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced the publication of two manuscripts that underscore the importance of integrating comprehensive genomic profiling with FoundationOne® into the management of patients with advanced lung cancer. Data from these studies demonstrate that comprehensive genomic profiling enabled identification of cancer-driving alterations that were or would have been missed by narrow, more limited hotspot testing. In both studies, researchers concluded that the discordant findings of the testing approaches underscore the fact that comprehensive genomic profiling consistently provides non-small cell lung cancer patients with more accurate and a broader range of treatment options, including clinical trials, versus narrow hotspot tests.

Findings from the two studies were published in *Oncotarget* and *Clinical Cancer Research.*

"Targeted therapies have revolutionized the treatment of lung cancer; however, for such therapies to be optimally matched to the right patients, there is an inherent mandate for comprehensive, highly accurate and sensitive clinical testing that can detect all actionable genomic alterations," said Mohamed Mohamed, M.D., Ph.D., co-director of the Thoracic Oncology Program, Cone Health Cancer Center in Greensboro, NC and co-author of the study published in *Clinical Cancer Research*. "Taken together, these studies reveal the inherent limitations of single-gene or hotspot testing, which fail to characterize the entire coding regions of cancer genes and detect all four classes of genomic alterations, thereby missing targeted therapy options that are often clinically relevant for treatment of advanced cancer."

Lung cancer is the leading cancer killer in both men and women in the United States[1]. An estimated 159,260 Americans died from lung cancer in 2014, accounting for approximately 27 percent of all cancer deaths[2]. There are two major types of lung cancer: non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). NSCLC is the most common and accounts for approximately 85 percent of all lung cancer cases[3]. Adenocarcinoma is the most common subtype of NSCLC.

"These studies demonstrate the clinical utility and the opportunity for improved clinical outcomes achieved by integrating comprehensive genomic profiling into clinical care for advanced non-small cell lung cancer," stated Byoung Chul Cho, M.D., Ph.D., associate professor, division of medical oncology, Yonsei Cancer Center and Department of Internal Medicine, Yonsei University College of Medicine in Korea and senior author of the study published in *Oncotarget*.

Key Findings Published in *Oncotarget*

The article, entitled "Genomic Profiling of Lung Adenocarcinoma Patients Reveals Therapeutic Targets and Confers Clinical Benefit When Standard Molecular Testing is Negative," was published online in the journal *Oncotarget* and demonstrates that maximally identifying actionable genomic alterations in advanced lung cancer patients is an important factor in improving clinical outcomes. Comprehensive genomic profiling using FoundationOne was performed on tumor specimens from 51 patients with advanced lung adenocarcinomas, which previously tested negative for the known driver oncogenes *EGFR, KRAS* and *ALK*. Key study findings include:

- 31 percent of patients harbored clinically relevant genomic alterations that were not previously discovered by the prior clinical testing.
- A genomic alteration with a corresponding targeted therapeutic based on the National Comprehensive Cancer Network (NCCN) guidelines was identified in 39 percent of patients. This data supports a previous finding by Drilon et al[4] showing 26 percent of previously negative NSCLC patients harbored a genomic alteration with a corresponding targeted therapy in NCCN guidelines.
- Genomic alterations for which clinical trials of targeted therapies could be considered were discovered in an additional 27 percent of patients. Similarly, in the study referenced above, Drilon et al demonstrated that 39 percent of NSCLC patients enrolled in that study harbored genomic alterations that could be linked to a clinical trial at the principal investigator's cancer center.

- Seven patients with *ROS1* rearrangements were enrolled in an ongoing trial assessing ceritinib, an inhibitor of activated *ROS1*. All but one of the patients who received ceritinib experienced objective responses.

Key Findings Published in *Clinical Cancer Research*

The article, entitled "Comprehensive Genomic Profiling Identifies Frequent Drug Sensitive *EGFR* Exon 19 Deletions in NSCLC Not Identified by Prior Molecular Testing," was published online in *Clinical Cancer Research* and highlights the importance of using comprehensive genomic profiling in advanced NSCLC to allow for sensitive detection of clinically relevant mutations. From a larger series of NSCLC cases assayed with FoundationOne in the course of clinical care, 400 consecutive cases harboring *EGFR* Δ*ex19* deletions were reviewed. Key study findings include:

- Pathology reports for 250 NSCLC cases harboring classic *EGFR* Δ*ex19* deletions identified by comprehensive genomic profiling were systematically reviewed. Of these, previous *EGFR* test results were available for 71 cases, and 17 percent had previously tested negative for *EGFR* mutation.
- In a subset of these patients with available clinical outcome information, treatment benefit with EGFR inhibitors was observed with *EGFR* TKI therapy.
- Of 14 NSCLC cases with an *EGFR* Δ*ex19* C-helical deletion, previous non-hybrid capture based *EGFR* sequencing results were available for six cases, and of these cases, five (83 percent) had negative prior testing.

"These studies show the discordant results between narrow sequencing and comprehensive genomic profiling with FoundationOne, implying that potentially clinically actionable targets may only be reliably detected when comprehensive genomic profiling is incorporated into clinical care," said Vincent Miller, M.D., chief medical officer, Foundation Medicine and co-author of the study. "As a result, advanced stage lung cancer patients are losing precious time with multiple rounds of hot spot and limited sequencing tests and ultimately, potentially missing critical opportunities to benefit from approved targeted therapies and clinical studies. We continue to provide evidence validating care efficiencies and clinical value that can be realized through use of our comprehensive genomic profiling approach at initial diagnosis of advanced lung 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 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 http://www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

Cautionary Note Regarding Forward-Looking Statements for Foundation Medicine

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 ability of comprehensive genomic profiling, including FoundationOne, to identify genomic alterations and improve patient outcomes; and the clinical relevance of comprehensive genomic profiling in cancer treatment. 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 risk that FoundationOne and Foundation Medicine's molecular information platform 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, 2015, which is on file with the Securities and Exchange Commission, as well as other risks detailed in 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] Centers for Disease Control and Prevention. National Center for Health Statistics. CDC WONDER On-line Database, compiled from Compressed Mortality File 1999-2012 Series 20 No. 2R, 2014.

[2] American Cancer Society. Cancer Facts and Figures, 2014.

[3] U.S. National Institutes of Health. National Cancer Institute: SEER Cancer Statistics Review, 1973-2006.

[4] www.aacrjournals.org, Drilon et al., *Broad, Hybrid Capture-Based Next Generation Sequencing Identifies Actionable Genomic Alterations in Lung Adenocarcinomas Otherwise Negative for Such Alterations by Other Genomic Testing Approaches*, American Association for Cancer Research, 2014.

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