

June 4, 2016

FoundationOne® Identifies Patients with Advanced Lung Cancer Likely to Respond or Develop Resistance to Certain RET Inhibitor Therapies

Data Underscore the Value of Molecular Information to Enable Informed Therapeutic Choices, Improved Outcomes and Efficient Clinical Care

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced new critical genomics data at the American Society of Clinical Oncology (ASCO) Annual Meeting 2016 demonstrating the clinical significance of comprehensive genomic profiling (CGP) with FoundationOne® in identifying patients with advanced lung cancer most likely to respond to *RET* inhibitor targeted therapies and also to predict those patients likely to develop resistance to targeted therapy.

Key Data Highlights:

The poster titled, "MDM2 amplification (Amp) to mediate cabozantinib resistance in patients (Pts) with advanced *RET*-rearranged lung cancers," presented by Romel Somwar, Ph.D., senior research scientist, pathology, Memorial Sloan Kettering Cancer Center, analyzes the genomic profiles of patients treated with the *RET* inhibitor, cabozantinib, to better understand the molecular mechanisms that underlie intrinsic and secondary resistance. Key study findings include:

- | Comprehensive genomic profiles were performed on 3,842 lung cancer patients, detecting concurrent MDM2 amplification in 20 percent of tumors with *RET* fusions
- | In *RET*-rearranged cell lines and xenografts treated with cabozantinib and the MDM2 inhibitors, AMG232 and RG7388, a combination of cabozantinib and AMG232 proved more effective at suppressing tumor growth than either agent alone
- | The study shows that MDM2 amplification is a potential mechanism of primary or acquired resistance to cabozantinib, and therefore MDM2 inhibitors might be studied clinically to prevent the development of acquired resistance and enable longer, more durable responses to treatment

The second poster presentation titled, "Significant systemic and CNS activity of *RET* inhibitor vandetanib combined with mTOR inhibitor everolimus in patients with advanced NSCLC with *RET* fusion," by Tina Cascone, M.D., Ph.D. and Vivek Subbiah, M.D., from The University of Texas MD Anderson Cancer Center, demonstrates that targeted combination therapy of vandetanib with the mTOR inhibitor, everolimus, was tolerable and demonstrated significant activity in *RET* rearranged NSCLC. Key study findings include:

- | Vandetanib and everolimus were administered to 13 stage IV NSCLC patients, including six patients with tumors harboring *RET* fusions
- | All six patients with *RET* fusions experienced a response, including five partial responses and one patient with stable disease
- | The six patients with *RET* fusions were identified using CGP with FoundationOne. Notably, two additional patients tested positive for *RET* fusions using FISH and did not respond to treatment.
- | The study suggests that combination therapy was superior to monotherapy with *RET* inhibitors, warranting further studies of this combination. The study further highlights the superior accuracy of CGP for calling fusions over traditional single gene tests, like FISH.

"By helping us better understand the likelihood of response and resistance to certain therapies, CGP is providing information that can help improve physician treatment decisions and ultimately, we believe, lead to better patient outcomes," said Vincent Miller, M.D., chief medical officer, Foundation Medicine. "Additionally, the sensitivity and accuracy of FoundationOne to reliably detect all classes of clinically relevant alterations in non-small cell lung cancer allow us to circumvent the false positives that often arise with single gene and standard hotspot testing. As this study shows, inaccuracies in genomic testing can lead to unnecessary and often unsuccessful treatments, as well as inefficient and costly care delivery."

Genomic alterations in the *RET* gene are found in several different types of cancer. *RET* gene fusions occur in 1 percent of

non-small cell lung cancers (NSCLC) and are well-established oncogenic drivers. The *RET* inhibitor agents, vandetanib and cabozantinib, have demonstrated antitumor activity in NSCLC patients harboring *RET* fusions, although data suggest that objective responses are observed in only a minority of patients, and progression-free survival (PFS) is shorter than with other oncogene targeted therapies in this disease. A portion of tumors may harbor intrinsic resistance to *RET* inhibitors, while some respond but eventually progress, yielding to the development of secondary resistance. However, molecular mechanisms that underlie resistance to cabozantinib are poorly understood. Taken together, these studies reinforce the critical importance of FoundationOne in identifying patients likely to respond to targeted therapies and to predict those patients likely to develop resistance.

Lung cancer is by far the leading cause of death among both men and women; about 1 out of 4 cancer deaths are from lung cancer¹. There are two major types of lung cancer: NSCLC and small cell lung cancer (SCLC). NSCLC is the most common and accounts for approximately 85 percent of all lung cancer cases². The American Cancer Society estimates there will be about 224,390 new cases of lung cancer in the United States for 2016 and about 158,080 deaths¹.

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 and sarcomas, provide a comprehensive 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).

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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; the ability of certain genomic alterations to predict whether a patient will respond to targeted therapies or develop resistance to targeted therapies and the longevity of response; the accuracy of comprehensive genomic profiling compared to other tests; the ability of FoundationOne to inform therapeutic choices and improve patient outcomes; and the relevance of comprehensive genomic profiling in oncology clinical care, including the ability to increase efficiencies in clinical care. 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 the results presented are found to lack scientific, medical or clinical utility or that subsequent research renders the results presented less useful or not useful in clinical practice; Foundation Medicine's services and 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 American Cancer Society. [Key Statistics for Lung Cancer](#).

² U.S. National Institutes of Health. National Cancer Institute: SEER Cancer Statistics Review, 1973-2006.

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