March 16, 2016

Foundation Medicine Presents New Data at the 2016 USCAP Annual Meeting Underscoring Importance of Comprehensive Genomic Profiling in Cancer Care

Latest Data Demonstrate the Clinical Utility of FoundationOne® in Brain and Breast Cancers to Complement Standard Pathology Practices in Improving Oncology Patient Outcomes with Targeted Therapy

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) and its collaborators presented new data in a variety of tumor types at the 2016 United States and Canadian Academy of Pathology (USCAP) Annual Meeting taking place March 12-18 in Seattle. The data further strengthens the growing body of evidence across various cancers in support of integrating comprehensive genomic profiling with FoundationOne® into the clinical pathology assessments of cancer patients to help inform targeted therapy utilization and improve patient care. The data presented underscore an urgent need for innovative solutions capable of accurately informing therapeutic options based on unique genomic alterations found within each patient's tumor. Oncology case reports and series have indicated positive responses to targeted therapies for certain rare tumor types, and additional evidence supporting clinical utility is evolving to support payor coverage.

"We are encouraged by the latest data presented amongst the global leaders and top minds in the pathology field at USCAP," said Jeffrey S. Ross M.D., medical director of Foundation Medicine, chair of pathology at the Albany Medical Center and lead author of two of the studies. "The pathology community is essential to advancing the next generation of novel therapies and personalized treatment for cancer patients worldwide. We are honored to provide an evidence-based platform to help the oncology community identify clinically relevant genomic alterations that hold the potential to influence patient treatment options, both for therapies that are FDA approved and therapies that are being investigated in clinical trials."

Three of the posters presented at the event focused on cancers with diverse, clinically relevant alterations, many of which are undetectable with standard screening, and represent indications with unmet clinical need, including refractory and metastatic breast cancer, triple negative breast cancer (TNBC) and adult and pediatric brain tumors. Results from all three data sets point to the importance of comprehensive genomic profiling to potentially influence and personalize treatment and guide the selection of approved targeted therapies or access to novel therapies that are being investigated in clinical trials.

Key Data Highlights:

The poster presentation titled, "Pangenomic Analysis of *BRAF* Genomic Alterations Across All Types of Brain Tumors Reveals Expanded Opportunities for Targeted Therapies," by Zachary R. Chalmers, lead researcher, senior research associate with Foundation Medicine, and presented by Dr. Ross demonstrates the need for additional basket-type clinical trials aimed to identify *BRAF* genomic alterations in various types of non-melanoma cancers to further understand targeted therapy choice and efficacy. Comprehensive genomic profiling using FoundationOne was performed to search for all classes of *BRAF* alterations in a large series of intracranial neoplasms including adult and pediatric brain tumors, and key findings include:

- 142 (4.8 percent) brain tumors featured *BRAF* alterations including base substitutions (70 percent), fusions (25 percent) and rare amplifications and other alterations types (5 percent). Genomic alterations in *BRAF* are widely distributed in brain tumors with base substitutions primarily seen in high-grade gliomas and *BRAF* fusions in low grade gliomas
- The presentation demonstrated that *BRAF* base substitutions and fusions can be successfully targeted with anti-*BRAF* and anti-MEK targeted therapies

Preliminary findings outlined in the poster presentation titled, "Genomic Alterations of *MCL1* is a Predictive Biomarker of Triple Negative Status and Therapy Response in Breast Cancer," led and presented by Dr. Ross, draw attention to the vital need for comprehensive analysis of breast cancer genes and the inherent limitations of hotspot testing in uncovering potential therapy options. Two hundred patients with breast cancer underwent comprehensive genomic profiling using FoundationOne, and key findings include:

- *MCL1* amplification is a frequent feature in advanced stage and high grade breast cancer, and *MCL1* amplified breast cancer is very seldom *ERBB2* co-amplified
    - Of the *MCL1* amplified breast cancer cases, 88 percent were high grade and 98 percent were stage IV at the

time of sequencing

- Of the 200 *MCL1* amplified breast cancer patients, 12 (6 percent) were *ERBB2* (*HER2*) amplified

- Clinical observation across several case studies suggest that treatment with targeted therapies including sorafenib and vorinostat in heavily pre-treated *MCL1* amplified breast cancer may be correlated with clinical benefit
- These preliminary findings suggest that *MCL1* amplified TNBC may benefit from combination targeted therapy, and warrant further investigation in a prospective clinical trial

Consistent with the other two data sets, the findings in the poster presentation titled, "The Detection of IHC-/FISH- *ERBB2* Non-Amplification Mutations in 5,606 Cases of Refractory and Metastatic Breast Cancer: an Emerging Opportunity for anti-HER2 Targeted Therapies," led by Siddhartha Dalvi, MBBS, lead researcher, Albany Medical College, and presented by Dr. Ross, demonstrate the potential for missing critical information with routine hotspot sequencing tests and thus the need for comprehensive profiling with FoundationOne. Comprehensive genomic profiling was performed on 5,606 metastatic breast cancer patients, and key findings include:

- *ERBB2mut* are responsible for nearly 20 percent of *ERBB2* alterations in metastatic breast cancer, though such mutations are not detectable by routine IHC and FISH slide-based *HER2* tests
- 698 (12.5 percent) featured *ERBB2* alterations, 596 (10.6 percent) featured *ERBB2* amplifications (*ERBB2amp*) and 137 (2.4 percent) featured *ERBB2mut*
- Evidence that *ERBB2mut* driven mBC are responsive to anti-HER2 targeted therapies is steadily accumulating

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).

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; the clinical relevance of comprehensive genomic profiling in cancer treatment, coverage and payment decisions by payors and the development of targeted therapies; and the potential of genomic profiling to assist pathologists. 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20160316005237/en/

Media Contact:
Pure Communications, Inc.
Dan Budwick, 973-271-6085
dan@purecommunicationsinc.com
or
Investor Contact:
Foundation Medicine, Inc.

Kimberly Brown, 617-418-2215
ir@foundationmedicine.com

Source: Foundation Medicine, Inc.