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## **Foundation Medicine Partners with Broad-based Coalition to Advance Revolutionary New Clinical Trial Design in Lung Cancer**

*Foundation Medicine Selected to Provide Comprehensive Genomic Testing Platform for Patients Enrolled in Master Protocol Trial*

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced that it has partnered with Friends of Cancer Research, as well as federal health and regulatory agencies, pharmaceutical companies, multiple cooperative groups and patient advocacy organizations to develop the clinical trial design for the "Master Protocol" study in patients with squamous cell carcinoma of the lung, a common subtype of non-small cell lung cancer, the leading cancer killer of men and women in the United States<sup>1</sup>. The Master Protocol is a biomarker-driven, multi-drug, multi-arm, multi-center Phase 2/3 registration trial, in which a comprehensive genomic testing platform will be used for all patients to determine stratification into appropriate target-specific arms of the trial. Foundation Medicine's fully informative genomic profile has been selected as the common platform in the Master Protocol to inform the investigational targeted therapy each patient will receive based on the molecular alterations present in their tumor.

Vincent Miller, M.D., chief medical officer at Foundation Medicine, will participate in a panel session today at the 2013 Friends-Brookings Conference on Clinical Research in Washington, D.C. to discuss the activation of the Master Protocol study and present final plans to begin enrolling patients in the trial in 2014. The panel also features leaders from key collaborators in the Master Protocol study, including: **Friends of Cancer Research; National Cancer Institute; Foundation for the National Institute of Health; U.S. Food & Drug Administration; and SWOG member institutions Yale Cancer Center, MD Anderson Cancer Center, University of California Davis Cancer Center, University of Colorado Cancer Center and Fred Hutchison Cancer Center.**

"We are excited to partner with leadership from some of our country's most innovative public and private organizations to advance the Master Protocol study and ultimately modernize the future of oncology clinical trials," stated Ellen V. Sigal, Ph.D., chairperson and founder, Friends of Cancer Research. "Foundation Medicine's comprehensive genomic platform is a critical component of the trial design, which requires the ability to identify all classes of genomic alterations across many different genes from one patient tissue sample, which ultimately informs the drug or drugs each patient will receive in the trial. This revolutionary clinical trial will provide a new perspective on our current system, saving time, money and lives. Our vision is that the concept and design of the Master Protocol study will serve as a model for future trials to accelerate the way new targeted therapies are developed and moved through the regulatory process to patients."

"It is challenging to recruit patients into clinical trials; the recruitment stage adds to the lengthy timeframes we currently face to bring investigational new drugs through the development process," said Roy S. Herbst, M.D. Ph.D., Ensign professor and chief of medical oncology, Yale Cancer Center and Smilow Cancer Hospital at Yale-New Haven, associate director for translational research, and clinical research program leader, Thoracic Oncology Program, Yale Cancer Center. "Another key feature of the Master Protocol study is that all cooperative groups will work together to enable rapid patient accrual and screen approximately 6,000 lung cancer patients over five years. The trial is designed with the ultimate goal of FDA approval for those drugs that meet pre-specified efficacy criteria, which has the potential to address the significant unmet need for new treatment options for patients with lung cancer."

The Master Protocol study is designed to address current issues in oncology drug development by bringing multiple investigational targeted therapies into one study under a single protocol to improve the efficiency, costs and success rates associated with moving investigational new drugs through the clinical development process, and ultimately expedite the timelines in which new treatment options are available to the patients who are most likely to benefit. Using a comprehensive genomic profile maximizes the amount of genomic information that can be obtained from a single patient tissue sample, and in turn, maximizes the likelihood that individuals will be successfully matched to a targeted therapy arm. It also reduces the need for pharmaceutical companies to use time and resources to identify a specific diagnostic partner to continue development of a targeted therapy.

"There is a fundamental shift in cancer care in which treatment options are informed by the molecular alterations driving a patient's cancer rather than solely from the anatomic site of origin," stated Dr. Miller. "Many new therapies in development are targeting alterations that are present in small percentages of patients, making it critical to confirm that the right patients are enrolled in a clinical trial to enhance the likelihood of success in the study and improve patient outcomes. To truly enable precision medicine in oncology, cancer patients must have broad access to comprehensive genomic testing in routine clinical care as well as oncology clinical trials, and we believe the Master Protocol study is an innovative step forward in this direction."

## 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](http://www.FoundationMedicine.com) or follow Foundation Medicine on Twitter (@FoundationATCG).

*Foundation Medicine® is a registered trademark, and FoundationOne™, is a trademark of Foundation Medicine, Inc.*

## 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 design, initiation and timing of the Master Protocol study; the use of Foundation Medicine's genomic profile as the common platform for the Master Protocol study; the ability of the Master Protocol study to address issues in oncology drug development; and the adoption of the Master Protocol study as a model for future oncology 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 the parties participating in the Master Protocol study may not have the resources to organize and implement the Master Protocol study, the Master Protocol study may not successfully address issues facing oncology clinical trials, Foundation Medicine is unable to achieve profitability, 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. American Cancer Society. *Cancer Facts & Figures 2012*.

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