# NEWS RELEASE

**FOR IMMEDIATE RELEASE**

**Foundation Medicine Announces New Data Using Next-Generation Sequencing to Detect Cancer-Related Mutations Not Identified by Conventional Methods**

*Data Presented at ASCO; New Pan-Cancer Test Reveals Actionable Genomic Tumor Alterations to Help Guide Clinicians in Therapeutic Decision-Making*

**CAMBRIDGE, MA and CHICAGO, IL, June 2, 2012** – Foundation Medicine, Inc., a molecular information company that brings comprehensive cancer genomic analysis to routine clinical care, today announced results from two studies using next-generation sequencing (NGS) to provide actionable information about genomic tumor alterations in individual patients' cancers across all solid tumor types. The studies, being presented this week in an oral and poster session at the 2012 Annual Meeting of the American Society of Clinical Oncology (ASCO), provide new evidence of the important role and clinical impact of NGS in cancer treatment.

These data follow Foundation Medicine's recent launch of FoundationOne™, the first pan-cancer, fully informative genomic profile for all solid tumors.

"These studies, along with other results previously presented and published, provide unequivocal evidence of the significant clinical value of NGS-based comprehensive genomic analysis," said Michael J. Pellini, president and chief executive officer, Foundation Medicine. "One test, using a very small amount of tissue, can enable physicians to tailor treatment to a patient's molecular subtype. With our pan-cancer genomic profile now commercially available, physicians will have a critical decision-making tool to assist them in making the most appropriate therapeutic choices for their patients with cancer."

The first study, *"Discovery of Recurrent KIF5B-RET Fusions and Other Targetable Alterations from Clinical NSCLC Specimens"* (Abstract # 7510), was completed in collaboration with researchers at Dana-Farber Cancer Institute and assayed cancer-relevant genes in 24 cases of non-small cell lung cancer (NSCLC). Highlights of the analysis include:

- 50 genomic alterations in 21 genes were identified using NGS, with at least one relevant alteration occurring in 83 percent of tumors.
- In 72 percent of the samples, at least one genomic alteration was associated with an available treatment or clinical trial of a targeted therapy.
- Researchers discovered a novel, recurrent *KIF5B-RET* gene fusion, which occurred in tumors lacking all other known oncogenic driver alterations. *KIF5B-RET*, when introduced into Ba/F3 cells, showed IL-3 independent growth consistent with oncogenic transformation.

- Preliminary sensitivity findings suggest that clinical trials are warranted to investigate the effect of multi-kinase inhibitors that inhibit RET (sunitinib, sorafenib and vandetinib) on tumors harboring the *KIF5B-RET* fusion.

"Many non-small cell lung cancers have oncogenic alterations that may be sensitive to a targeted therapeutic approach, which can lead to better outcomes for individual patients," said Marzia Capelletti, Ph.D., Research Fellow in Medicine, Dana-Farber Cancer Institute. "The challenge for physicians is to comprehensively understand the patient's cancer by characterizing the genomic profile and develop a rational treatment strategy. The results of this study clearly demonstrate that there is a need to have a reliable tool to identify the particular molecular drivers of a tumor to help select appropriate therapies for individual patients."

An additional study, *"Next-Generation Sequencing Reliably Identifies Actionable Genomic Changes in Common and Rare Solid Tumors: The FMI Experience with the Initial 50 Consecutive Patients"* (Abstract #10590), utilized NGS to identify actionable genomic alterations across a variety of solid tumors in the first 304 clinical specimens (poster updated with clinical experience through May 1, 2012) analyzed by Foundation Medicine's CLIA-approved laboratory. Alterations were defined as actionable if linked to an approved therapy in the tumor under study or another solid tumor; a known or suspected contraindication to a given therapy; or a clinical trial linked to the alteration. Lung, breast, colorectal, ovarian and pancreatic cancers were the most common solid tumors identified among 16 primary tumor types. In the analysis:

- Investigators reported that of 304 samples analyzed, 292 were successfully reported, for a failure rate of only 4%.
- Of the reported samples, 77% (224/292) had at least one actionable alteration.
- Additionally, 59% (172/292) had at least one actionable alteration that would not have been detected by commonly available molecular assays.
- Among the reported samples in the three most common tumor types, 52/61 lung samples (85%), 43/50 breast samples (86%), and 28/31 colon samples (90%) had at least one actionable alteration.
- There were a total of 193 unique actionable alterations found in this data set.

"The complex nature of cancer and the transformation of cancer care, prompted by advanced understanding of genomic subtypes and emergence of targeted therapies, make the detection of alterations to guide therapeutic decision-making more critical than ever," said Gary Palmer, M.D., J.D., M.P.H., senior vice president of medical affairs and commercial development, Foundation Medicine, and lead author of the study. "This NGS assay makes it possible for clinicians to make the best possible therapeutic choices, minimize the use of ineffective therapies and enhance enrollment in clinical trials appropriate for the individual patient."

Foundation Medicine's first commercial offering, FoundationOne, is a fully informative genomic profile that allows any oncologist to use the same technology that informed the studies presented here as a clinical decision making tool in their own practice. FoundationOne uses routine, formalin-fixed, paraffin-embedded tumor samples. Test results are provided in a

straightforward report that matches detected patient's genomic alterations with potential treatment options and clinical trials.

**About FoundationOne™**
FoundationOne is a fully informative genomic profile that complements traditional cancer decision tools and often expands treatment options by matching each patient with targeted therapies that may be relevant to the molecular changes in their tumor. Using next-generation sequencing, FoundationOne interrogates all genes somatically altered in human cancers that are validated targets for therapy or unambiguous drivers of oncogenesis based on current knowledge. It reveals all classes of genomic alterations including base substitutions, insertions, deletions, copy number alterations and select rearrangements. Each patient's genomic profile is reported to the physician matched with targeted therapies and clinical trials that may be relevant based on the molecular blueprint of their tumor. Results are supported by the latest scientific and medical evidence. FoundationOne has been optimized to fit easily into the clinical workflow of a practicing oncologist. It is available for all solid tumors and clinical grade results can be obtained from as little as 50ng of DNA obtained from formalin-fixed, paraffin-embedded tumor tissue samples. FoundationOne is a laboratory-developed test performed at Foundation Medicine's CLIA-certified facility and is currently available for all solid tumor types. Please visit www.foundationone.com for more information.

**About Foundation Medicine**
Foundation Medicine 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 has developed FoundationOne, 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 the company's website www.foundationmedicine.com.



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