



NEWS RELEASE

FOR IMMEDIATE RELEASE

Contact:

Sheryl Seapy
Pure Communications, Inc.
(949) 608-0841

Foundation Medicine Announces Results Using Next-Generation Sequencing to Detect Cancer-Associated Mutations in Routine Cancer Tissue Samples; Data Presented at ASCO

Approach Identifies More Actionable Alterations than Conventional Methods; Demonstrates Potential for Clinical Use of Comprehensive Cancer Genomic Testing

CAMBRIDGE, Mass. and CHICAGO, Ill. – June 6, 2011 – [Foundation Medicine, Inc.](#), a cancer diagnostics company that aims to bring comprehensive cancer genome analysis to routine care, today announced key results using Next-Generation Sequencing (NGS) to perform molecular profiling in routine formalin-fixed paraffin-embedded (FFPE) cancer specimens. Study results were 100 percent concordant with conventional, single gene analysis previously reported by commercial reference laboratories for *BRAF*, *KRAS* and *EGFR*. The test also detected many other known and novel mutations, many of which may be clinically actionable. These data are being presented today in a poster session at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO), abstract number 10564.

“Cancer is a complex disease driven by multiple genomic subtypes that are unique to each patient, and these factors inform how the cancer responds to treatment,” said Jeffrey S. Ross, M.D., Cyrus Strong Merrill Professor & Chair, department of pathology & laboratory medicine, Albany Medical College and lead author of the study. “This study not only confirms that clinical grade NGS can be applied to routine cancer specimens to identify alterations that may be relevant to therapeutic decision-making, but this approach also identifies many more potentially actionable alterations than conventional single gene analysis. This test has the potential to significantly benefit the medical community and cancer patients by informing optimal cancer therapy selection.”

The study evaluated DNA extracted from 75 cancer tissue samples in three cohorts (non-small cell lung cancer (NSCLC), melanoma and colon cancer). Specimen types included major resections, incisional biopsies, needle core biopsies and fine needle aspirates (FNAs). Key highlights from the study include the following:

- Sequence analysis with the comprehensive cancer diagnostic test achieved an average coverage of ~200X and 100% concordance with conventional single-gene analysis for *BRAF* (melanoma), *KRAS* (colon) and *EGFR* (lung) mutations performed by commercial reference laboratories;

- The test identified a total of 214 driver mutations (including multiple mutations in well-known cancer genes such as *TP53*, *STK11*, *APC*, *CDHI*, *ATM*, *GNAS*, *SMAD4*, *PIK3CA*, *KIT*, *MDM2* and *CDKN2A*), of which only 37 (17.3%) could have been detected by conventional hot-spot analyses;
- More than 50% of specimens studied had mutations that could inform therapeutic decision-making.

“The level of sensitivity, specificity and coverage achieved from routine FFPE clinical specimens with our NGS-based test is unprecedented,” said Michael J. Pellini, M.D., president and chief executive officer of Foundation Medicine. “This data demonstrates a profound advance towards comprehensive cancer diagnostics. As the underlying molecular drivers of cancer are better understood, and more targeted therapies are developed to target those drivers, it has become necessary to perform a comprehensive molecular analysis of a patient’s tumor with one test. Foundation Medicine’s test can serve as a helpful decision-making tool for physicians to recommend cancer treatment approaches tailored to each patient’s molecular subtype. As we approach broad commercialization of the test next year, we look forward to sharing additional data supporting the use of NGS-based comprehensive genomic analysis in routine cancer care.”

To date, Foundation Medicine has performed its test on lung, colon, breast, endometrial, breast, GI, salivary, liver, kidney, soft tissue sarcomas, esophageal, gastric neuroendocrine tumors and basal cell carcinoma. The company is preparing for CLIA approval in 2011 and a national commercial launch of its cancer diagnostic test in 2012.

About the Study

DNA was extracted from 40 µm of tissue for 49 colorectal cancer, 22 NSCLC and 4 melanoma FFPE tissue blocks. 200 ng of DNA was used to perform paired-end sequencing on the Illumina HiSeq™ 2000 platform for 2574 exons representing 176 genes captured using Agilent SureSelect™ baits. Comprehensive variant profiles were generated for each sample, including base substitutions, insertions/deletions, copy number alterations and targeted rearrangements.

About Foundation Medicine

Foundation Medicine is dedicated to the development of a comprehensive diagnostic test that improves cancer care by helping physicians personalize treatment for their patients. Foundation Medicine’s laboratory test is being designed to accommodate a broad landscape of cancer genome information and a growing repertoire of more targeted treatments and clinical research opportunities. Foundation Medicine’s test will assist physicians to make prompt and informed determinations about the best cancer treatments and clinical trial options for each patient, taking into account each patient’s unique cancer-associated alterations alongside publicly available scientific and medical information. The company’s founding advisors are world leaders in genome technology, cancer biology and medical oncology; they, alongside clinicians, biotech and molecular diagnostics industry leaders, are working to harness emerging technologies to develop unparalleled tests that will identify and interpret an ever-growing set of actionable genomic alterations, truly enabling personalized cancer medicine. For more information, please visit the company’s website at www.foundationmedicine.com.

###