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New Clinical Data Identifies High Frequency of *HER2* Alterations across Multiple Solid Tumor Types using FoundationOne™

Data presented at ASCO highlight potential for broad genomic profiling approach to help inform patient treatment options and accelerate clinical trial accrual

CAMBRIDGE, Mass. and CHICAGO - June 2, 2013 -- Foundation Medicine, Inc., a molecular information company that brings comprehensive cancer genomic testing and analysis to routine clinical care, today announced data demonstrating that its comprehensive genomic profile for cancer, FoundationOne™, was able to identify an unprecedented number of actionable genomic alterations, including a significant number of *HER2* (*ERBB2*) amplifications and non-amplification alterations, across 14 different solid tumor types. The study suggests that a comprehensive genomic profile can be used across many tumor types to better understand the frequency of actionable genomic alterations, defined as an alteration that is directly linked to an approved targeted treatment option or a mechanism-driven clinical trial. This approach is also clinically important, potentially enabling more rapid accrual to clinical trials and additional treatment options for some patients with cancer.

"Our clinical experience to date shows that traditional single-gene assays or limited panels may miss actionable alterations for some patients with cancer," said Michael J. Pellini, M.D., president and chief executive officer, Foundation Medicine. "A comprehensive approach, such as FoundationOne, could assist physicians in identifying targeted therapy options that may be relevant based on the molecular changes that contribute to a patient's disease."

Data presented today in an oral session (*An analysis of ERBB2 alterations (amplifications and mutations) found by next-generation sequencing (NGS) in 2,000+ consecutive solid tumor (ST) patients*; abstract #11000), by Massimo Cristofanilli, M.D., Thomas Jefferson University - Kimmel Cancer Center at the 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO), demonstrate the potential for additional clinical insights gained from using FoundationOne across a broad array of solid tumor types.

"These data contribute to the growing body of clinical evidence suggesting that each metastatic tumor, regardless of the organ of origin, often has a potentially actionable genomic profile," said Dr. Cristofanilli. "The use of FoundationOne in patients with advanced solid tumors revealed potentially actionable HER2 alterations that were unexpected based on current literature and would not have been detectable by existing technologies used to detect HER2 alterations (FISH and IHC)."

Techniques such as FISH and IHC are routinely used to test patients with breast and gastro-esophageal cancers for amplification or overexpression of the HER2 protein, but patients with other solid tumors are not routinely screened for alterations in this gene. Researchers in this study analyzed the results from a series of 2,221 consecutive clinical solid tumor samples profiled by Foundation Medicine to determine the frequency of *HER2* alterations, which may have implications for clinical trial enrollment or treatment options for these patients.

The assay identifies all classes of genomic alterations - including base substitutions, copy number alterations, short insertions/deletions, and rearrangements - in 3,230 exons of 182 cancer-related genes, as well as introns of 14 genes involved in rearrangements and fusions (FoundationOne was updated in December 2012 to include 3,734 exons of 236 cancer-related genes, as well as introns of 19 genes often rearranged or altered in cancer). Study results identified at least one *HER2* alteration in 4.9% of specimens of which >40% were alterations in *HER2* unamplified samples that would be missed by IHC and FISH. In all, 14 solid tumor types had evidence of *HER2* alterations, including 29% of esophageal carcinomas, 20% of uterine carcinomas, 14% of breast carcinomas and 12% of stomach carcinomas, suggesting that these patient's tumors may be sensitive to anti-HER2 targeted therapies.

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 a comprehensive review of published literature. 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'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 or follow Foundation Medicine on Twitter (@FoundationATCG).

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