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Actionable Genomic Alterations Identified in 76% of Clinical Cancer Cases Profiled with FoundationOne™

Approach Has Led to Identification of New, Potentially Druggable Gene Fusions as well as Known Alterations in Novel Tumor Types; Data Presented at ASCO 2013

CAMBRIDGE, Mass. and CHICAGO - May 31, 2013 -- [Foundation Medicine, Inc.](#), a molecular information company that brings comprehensive cancer genomic testing and analysis to routine clinical care, today announced new data demonstrating that its comprehensive genomic profile, [FoundationOne™](#), was able to identify actionable alterations in 76.4% (1,614/2,112) of clinical tumor specimens profiled. Notably, 61.5% (1,298/2,112) of FoundationOne reports revealed actionable alterations that would not have been identified by currently available hotspot panel tests. These data will be presented in a poster discussion session (*Use of next-generation sequencing (NGS) to identify actionable genomic alterations (GA) in diverse solid tumor types: The Foundation Medicine (FMI) experience with 2,200+ clinical samples*) at the 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO), abstract number 11020.

"Oncology has been transformed by the linkage of genomic alterations in known cancer-related genes with targeted therapeutics," said Michael J. Pellini, M.D., president and chief executive officer, Foundation Medicine. "FoundationOne helps physicians deliver on the promise of precision medicine by matching the genomic profile of each patient's tumor with potential targeted therapies or clinical trials that may not be otherwise identified. Data presented at ASCO provide further evidence that FoundationOne may often reveal new, rational treatment options for patients with cancer."

Foundation Medicine consecutively analyzed 2,221 patients' tumors in the company's CLIA-certified lab in Cambridge, Mass. In this group of clinical cases, 95.1% (2,112/2,221) of specimens were successfully profiled at a mean coverage of 1134X. Seventy-six percent of these cases harbored one or more actionable genomic alterations, defined as an alteration that is directly linked to an approved targeted treatment option or a mechanism-driven clinical trial. As referenced in the poster, this approach has led to new insights into advanced cancer including: 13 novel, potentially druggable kinase gene fusions; alterations in known drug targets (e.g. *ALK*, *EGFR*, *ERBB2*, *KIT*, *MET*, *RAF1* and *RET*), in novel tumor types, as well as new mechanisms of resistance to approved targeted therapies. Two case studies have recently been published highlighting patients who demonstrated dramatic responses to treatment with targeted therapies identified using their tumor genomic profile ^{1, 2}. Complete results will be presented on Monday, June 3, 2013 from 8:00 a.m. - 12:00 p.m. CT during the Tumor Biology Poster Discussion Session (Room S102, abstract number 11020).

Additional Posters and Discussions

Foundation Medicine and its collaborators will also present two oral discussions and eight additional posters during ASCO. The posters and oral presentations include analysis of clinical case cohorts in a range of tumor types and, collectively, provide new and compelling evidence suggesting that Foundation Medicine's comprehensive genomic profile can be used as part of a clinical oncology workup and may provide new, actionable information that may help physicians and their patients evaluate targeted treatment and clinical trial options. Please visit www.foundationone.com/data for a reference list of abstracts related to FoundationOne.

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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