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Foundation Medicine Launches FoundationOne™

First broad clinical application of next-generation sequencing to aid in the identification of treatment options for patients with cancer

CAMBRIDGE, MA —May 30, 2012— Foundation Medicine announced today the commercial launch of FoundationOne™, the first pan-cancer, fully informative genomic profile designed to help oncologists expand their patients' treatment options. FoundationOne is optimized to fit current oncology practice. It uses clinical-grade, next-generation sequencing to interrogate hundreds of cancer-related genes from routine, formalin-fixed, paraffin-embedded tumor samples. Test results are provided in a straightforward report that aligns detected genomic alterations with potential treatment options and clinical trials.

"The launch of FoundationOne marks an important moment in the field of oncology," said Michael J. Pellini, M.D., Foundation Medicine's chief executive officer. "This first commercial product from Foundation Medicine is the result of a convergence of genomic sequencing, information technology and clinical practice that would not have been possible at any other point in history. Foundation Medicine is the first company with the ability to put these advances into everyday care, giving oncologists the molecular blueprint of each patient's cancer to help inform a more targeted treatment strategy."

FoundationOne interrogates all genes somatically altered in human solid tumors that are validated targets for therapy or 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. Genomic profile results are reported to the physician for each individual patient along with targeted therapies and clinical trials that may be relevant based on the specific alterations identified in the patient's tumor and the most recent scientific and medical evidence.

"FoundationOne brings a best-in-class molecular diagnostic to all oncologists and pathologists, both in the community where most patients are treated and at major academic centers," said Vincent Miller, M.D., senior vice president of clinical development, Foundation Medicine. "FoundationOne gives physicians a powerful new tool to help them incorporate the latest genomic findings into treatment decisions for each patient. The commercial availability of FoundationOne is perfectly timed to accelerate the clinical adoption of the burgeoning molecular information in oncology."

Early clinical studies with FoundationOne have demonstrated high accuracy and an ability to interrogate all classes of potentially actionable alterations to reveal clinically-relevant information[1-2]. Since receiving CLIA certification in October, 2011 and beginning pre-launch operations, Foundation Medicine has shown that FoundationOne reveals, on average,

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[1] Ross J., et al. (June 2011) Comprehensive next-generation sequencing for clinically actionable mutations from formalin-fixed cancer tissues. June 2011. Poster presented at the American Society of Clinical Oncology Annual Meeting.

[2] Yelensky, R., et al. (April 2012) Massively parallel sequencing of clinical FFPE cancer specimens enables comprehensive genomic assessment of patient eligibility for targeted therapy. April 2012. Oral presentation at American Association for Cancer Research Annual Meeting.

approximately three reportable alterations per patient sample and three times as many actionable alterations than the most comprehensive “hot spot” panels or tests currently available[3]. FoundationOne sequences hundreds of genes known to be clinically relevant in cancer and identifies any actionable alterations, whereas existing technologies are able to find only pre-determined alterations. Experience to-date shows that FoundationOne can identify previously undetectable, yet potentially actionable, alterations, and suggests that FoundationOne will profoundly increase the application of molecular information in clinical practice.

Foundation Medicine was founded in 2010 by world leaders in the fields of cancer genomics, cancer biology, clinical oncology, and information sciences from Harvard Medical School, Massachusetts Institute of Technology, The Dana-Farber Cancer Institute and The Eli and Edythe L. Broad Institute. The company is funded by Third Rock Ventures, Kleiner Perkins Caufield & Byers and Google Ventures.

About FoundationOne™
FoundationOne is a fully informative genomic profile that complements traditional cancer decision tools and often expands treatment options by matching patients 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 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 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. Please visit www.foundationmedicine.com for more information

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[3] Palmer, G. et al. (June 2012). Next-generation sequencing (NGS) to identify actionable genomic changes in common and rare solid tumors: The FMI experience with the initial 50 consecutive patients. Abstract accepted for presentation at the American Society of Clinical Oncology Annual Meeting.