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Foundation Medicine and Collaborators Identify High Incidence of Genomic Alterations Linked to Targeted Therapies in Liver Cancer; Data Published in The Oncologist

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Foundation Medicine, Inc.](#) (NASDAQ: FMI) today announced the results of a new study demonstrating that FoundationOne™ identified genomic alterations linked to targeted therapies or clinical trials in 71% (20/28) of patients with intrahepatic cholangiocarcinoma (ICC). ICC is a form of primary liver cancer that is rapidly increasing in incidence, typically associated with poor prognosis and often treated with systemic, non-targeted therapies extrapolated from treatments used in other gastrointestinal cancers. These results suggest that FoundationOne may be used to inform targeted treatment options for ICC patients based on the molecular profile of their tumor. The data were published in the current edition of *The Oncologist*.¹

"In the past several years, the field of oncology has been transformed by discoveries of genomic alterations across many tumor types which may be linked to treatment options," said Daniel Catenacci, M.D., assistant professor of medicine, University of Chicago, and co-author of the study. "Comprehensive genomic profiling with FoundationOne is especially critical to advance care for patients with rare or understudied cancers, such as ICC, in which molecular alterations may be present that can lead to targeted therapeutic options or clinical trials which may not have otherwise been considered."

In this study, comprehensive genomic profiling using FoundationOne was conducted on formalin-fixed paraffin-embedded clinical tumor samples from 28 patients diagnosed and being treated for ICC. More than two-thirds of patients (71%) harbored at least one potentially actionable alteration, including FGFR2 (14%), KRAS (11%), PTEN (11%), CDKN2A (7%), CDK6 (7%), ERBB3 (7%), MET (7%), NRAS (7%), BRCA1 (4%), BRCA2 (4%), NF1 (4%), PIK3CA (4%), PTCH1 (4%) and TSC1 (4%). The most commonly observed alterations occurred within ARID1A, IDH1/2 and TP53 (36% each). Researchers also found that MCL1 was amplified in 21% of samples.

"Clinical cancer care is undergoing a paradigm shift in which treatments can be tailored to the molecular alterations identified in a patient's tumor instead of solely focusing on where the tumor originated in the body," said Jeffrey S. Ross, M.D., medical director, Foundation Medicine, and lead author of the study. "For cancers like ICC, which have no approved treatments, the ability to identify the genomic alterations driving a patient's cancer has the potential to elucidate previously unavailable treatment options and address unmet clinical needs for these patients."

Dr. Ross is also the Cyrus Strong Merrill Professor and chair of the Department of Pathology and Laboratory Medicine at Albany Medical Center. Foundation Medicine conducted this study in collaboration with Albany Medical College, University of Chicago and The University of Texas MD Anderson Cancer Center.

About FoundationOne™

FoundationOne, the company's first clinical product, is a fully informative genomic profile used by oncologists to identify the molecular alterations in a patient's tumor and match those alterations with relevant targeted therapies and clinical trials. Using next-generation sequencing in routine cancer specimens, 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. FoundationOne fits easily into the clinical workflow of the ordering physician, and test results are provided in an easy-to-interpret report supported by a comprehensive review of published literature. FoundationOne is a laboratory-developed test performed at Foundation Medicine's CLIA-certified lab. Please visit www.FoundationOne.com for more information.

About Foundation Medicine

Foundation Medicine® (NASDAQ: FMI) 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 clinical assays, FoundationOne™ for solid tumors and FoundationOne™ Heme for hematologic malignancies, sarcomas and pediatric cancers, each provide a fully informative genomic profile to identify the molecular alterations in a patient's tumor 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).

Foundation Medicine® is a registered trademark, and FoundationOne™ is a trademark of Foundation Medicine, Inc.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the use of FoundationOne™ to identify potentially actionable genomic alterations linked to targeted therapies for patients with intrahepatic cholangiocarcinoma (ICC). All such forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include the risks that additional studies of FoundationOne may not replicate the results of the study involving ICC; that targeted treatment options identified by FoundationOne for ICC may not be available; that delays or denials in obtaining coverage and reimbursement decisions for FoundationOne, FoundationOne Heme and subsequent products may occur; that Foundation Medicine may not achieve profitability, compete successfully, manage its growth, or develop its molecular information platform; and the risks described under the caption "Risk Factors" in Foundation Medicine's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, which is on file with the Securities and Exchange Commission, as well as other risks detailed in Foundation Medicine's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Foundation Medicine undertakes no duty to update this information unless required by law.

1. Ross, J.S. et al. New Routes to Targeted Therapy of Intrahepatic Cholangiocarcinomas Revealed by Next-Generation Sequencing. *The Oncologist* first published February 21, 2014; doi:10.1634/theoncologist.2013-0352.

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