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Comprehensive Genomic Profiling with FoundationOne® Guides Targeted Therapeutic Choices and Clinical Responses in Challenging Biliary Tract Cancers

CAMBRIDGE, Mass. & CHICAGO--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today presented new data including promising clinical outcomes underscoring the importance of integrating comprehensive genomic profiling with FoundationOne® into clinical oncology care for the treatment of biliary tract cancers. Foundation Medicine conducted comprehensive genomic profiling of tumor samples from 554 patients with a broad range of advanced biliary tract cancers and determined that two-thirds of patients harbored clinically relevant genomic alterations, which could potentially influence and personalize treatment and guide the selection of approved targeted therapies or access to novel therapies available in clinical trials.

Given the limited treatment options and poor prognosis of patients with advanced biliary tract cancers and the diversity of clinically relevant alterations identified, comprehensive genomic profiling appears to have significant potential to maximize the identification of new treatment paradigms and address an unmet clinical need for this devastating disease. These data, including select case studies highlighting clinical benefit in patients, were presented today in an oral presentation at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting titled, "Comprehensive Genomic Profiling Of Biliary Tract Cancers Reveals Tumor-Specific Differences and a High Frequency of Clinically Relevant Genomic Alterations" (abstract #4009), by Milind Javle, M.D., Professor, Department of Gastrointestinal (GI) Medical Oncology, Division of Cancer Medicine, University of Texas MD Anderson Cancer Center.

"Biliary tract cancers are often not diagnosed until advanced stage disease, and unfortunately, many are refractory to conventional therapies, such as radiation treatment and chemotherapy, making them difficult to treat," said Dr. Javle. "These data present a new and critical understanding of the genomic alterations that are frequently present in biliary tract cancers, and highlight their heterogeneity. The identification of targetable genomic alterations is one of the most significant clinical advances in management of these cancers, particularly in the case of cholangiocarcinoma."

Key Data Highlights:

Foundation Medicine conducted comprehensive genomic profiling of tumor samples from 412 intrahepatic cholangiocarcinoma (IHCCA), 57 extrahepatic cholangiocarcinoma (EHCCA) and 85 gall bladder cancer (GBCA) patients. Select case studies of patients with biliary tract cancers were presented as part of the presentation, including the following:

- A 67-year-old male with IHCCA had progressed on conventional chemotherapy. FoundationOne detected a *BRAF* mutation, and after eight weeks of *BRAF* inhibitor therapy, his liver metastases decreased in size. The metastases continued to decrease after an additional eight weeks of treatment.
- A 71-year-old female with metastatic GBCA was found to harbor a *FGFR3-TACC3* fusion and was treated with dovitinib therapy. After four months, CT images demonstrate disease stabilization.
- A 64-year-old female with recurrent GBCA was found to have amplification of *ERBB2* and was given trastuzumab and chemotherapy. After eight months of treatment, her tumors remain stable.
- A 67-year-old woman with GBCA developed liver metastases, and FoundationOne revealed amplification of *EGFR*, amplification of *CCND1*, and mutations in *PIK3CA* and *TP53*. She was given erlotinib in combination with systemic therapy, resulting in a reduction in tumor size.

Further, results of comprehensive genomic profiling showed the following:

- IHCCA, EHCCA and GBCA share frequent genomic alterations in cell cycle regulation (*CDKN2B*) and chromatin remodeling (*ARID1A*).
- IHCCA is further characterized by *FGFR* fusions, *IDH1/2* substitutions, *BRAF* substitutions and *MET* amplification with a low *KRAS* mutation frequency.
- EHCCA and GBCA have frequent *ERBB2* amplifications (GBCA > EHCCA) and *PIK3CA/MTOR* pathway alterations.
- *KRAS* mutation frequency is high in EHCCA and low in GBCA.
- In the case of some mutations, including *KRAS, BAP1* and *FGFR,* there is a correlation with cancer prognosis. This has

important implications regarding the choice of therapy.

"This study is unique and encouraging both in the understanding of unique genomic drivers across broad biliary tract cancers and for the identification of several targeted therapies with the potential to deliver improved outcomes," said Jeffrey S. Ross M.D., Medical Director of Foundation Medicine, Chair of Pathology at the Albany Medical Center and lead author of the study. "Given the limited treatment options and poor prognosis associated with these cancers, we believe these data support the integration and reimbursement of comprehensive genomic profiling into the cancer treatment pathway for individuals with biliary tract cancer."

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 and sarcomas, provide a comprehensive genomic profile to identify the molecular alterations in a patient's cancer 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 http://www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

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 ability of FoundationOne to identify clinically relevant genomic alterations, the benefits to patients of comprehensive genomic profiling of their tumors, the utility of FoundationOne in informing treatment of certain patient populations, the ability of FoundationOne to affect the prognosis, treatment or diagnosis of cancer patients, and clinical data related to FoundationOne. 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 Foundation Medicine's products will not be able to identify genomic alterations in the same manner as prior clinical data; and the risks described under the caption "Risk Factors" in Foundation Medicine's Annual Report on Form 10-K for the year ended December 31, 2014, 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.

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