June 5, 2016

Foundation Medicine Presents New Data at ASCO 2016 Demonstrating that FoundationOne® May Help Predict Response to Cancer Immunotherapy Across a Variety of Advanced Cancers

Molecular Information on Tumor Mutational Burden Supports Improved Outcomes and Drives Care Efficiencies

CAMBRIDGE, Mass. & CHICAGO--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) and it collaborators presented data showing that higher tumor mutational burden, as estimated by comprehensive genomic profiling with FoundationOne®, successfully predicted a greater likelihood of response and longer response duration to cancer immunotherapies in patients with advanced bladder cancer and metastatic melanoma as well as several other tumor types. The results were presented in two oral sessions, and several poster discussions at the 2016 Annual Meeting of the American Society of Clinical Oncology (ASCO) taking place in Chicago.

"Successful application of cancer immunotherapy in the clinic is one of the most important advances in cancer treatment in decades," said Vincent Miller, M.D., chief medical officer at Foundation Medicine. "These data suggest that tumor mutational burden could serve as an independent predictive biomarker to aid clinicians in identifying patients who are most likely to benefit from cancer immunotherapies that target either the PD-1 or PD-L1 proteins."

Cancer immunotherapy works by helping the immune system mount an effective anti-cancer response, a process that depends in part on the recognition of cancer-specific proteins called neoantigens. Tumor mutational burden has been shown to correlate well with the number of neoantigens, and therefore it may help identify patients most likely to respond to cancer immunotherapies. By combining comprehensive genomic profiling of 315 genes utilizing the FoundationOne assay, with Foundation Medicine's advanced and proprietary algorithm that filters out normal individual genomic variants, FoundationOne can reliably and accurately measure tumor mutational burden without the need for whole exome sequencing. Foundation Medicine expects to provide a CLIA-certified version of tumor mutational burden on all FoundationOne and FoundationOne® Heme reports to physicians in the third quarter 2016.

Overview of Data Presentations

The IMvigor 210 study of Tecentriq™ (atezolizumab; anti-PD-L1; Genentech/Roche) in locally advanced or metastatic urothelial carcinoma evaluated three separate biomarkers: PD-L1 protein expression as measured by immunohistochemistry, molecular subtype as measured by gene expression and The Cancer Genome Atlas, and mutational load (often referred to as tumor mutational burden) as measured by FoundationOne. All three biomarkers were shown to be independent predictors of response to Tecentriq.

- "PD-L1 Expression, Cancer Genome Atlas (TCGA) Subtype and Mutational Load are Independent Predictors of Response to Atezolizumab (atezo) in Metastatic Urothelial Carcinoma (mUC; Imvigor210)", by Jonathan E. Rosenberg, M.D., Memorial Sloan Kettering Cancer Center [Abstract #104, Clinical Science Symposium, Sunday June 5, 9:57-10:09 AM].

"These results are particularly exciting given the amount of variability inherent to using immunohistochemistry (IHC) to measure biomarkers. There are many different PD-L1 IHC tests, for example, and pathologists often do not see agreement between them," stated Vamsidhar Velcheti, M.D., assistant professor, Solid Tumor Oncology, Taussig Cancer Institute, Cleveland Clinic. "We need a truly quantitative and reproducible approach to predicting response to immunotherapies, and measuring tumor mutational burden using FoundationOne may provide us with that solution."

In a separate melanoma study, higher mutational burden as measured by FoundationOne was associated with a greater likelihood of response and a more durable response to pembrolizumab; anti-PD-1; Merck, nivolumab; anti-PD-1; Bristol Myers Squibb, and Tecentriq, thereby providing oncologists with greater confidence in the potential for clinical benefit from a host of newly approved immunotherapies.

- "Hybrid Capture-Based Next Generation Sequencing (HC NGS) in Melanoma Identifies Markers of Response to Anti-PD1/PD-L1", by Douglas Buckner Johnson, M.D., M.S.C.I., Vanderbilt-Ingram Cancer Center [Abstract #105, Clinical Science Symposium, Sunday June 5, 10:21-10:33 AM]

Dr. Miller continued, "The clinical reality is that some patients respond very well to cancer immunotherapies and others do not. As a result, the ability to leverage our molecular information platform to identify the right candidates for these immunotherapies is an important advance for the field of precision medicine. Matching the right therapy with the right patient has the potential to both improve outcomes and increase efficiency in the current care model."

These conclusions were further supported by two additional presentations at ASCO 2016 that demonstrated that total mutational burden could also predict response to cancer immunotherapy in lung and colorectal cancers:

- "Total Mutational Burden (TMB) in Lung Cancer and Relationship with Response to PD-1/PD-L1 Targeted Therapies", by David R. Spigel, M.D., Sarah Cannon Research Institute [Abstract #9017, Poster Session, Saturday June 4, 8:00-11:30 AM].
- "Tumor Mutational Burden as a Potential Biomarker for PD1/PD-L1 Therapy in Colorectal Cancer", by Thomas J. George, M.D., F.A.C.P., University of Florida [Abstract #3587, Poster Session, Saturday June 4, 8:00-11:30 AM].

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 offers a full suite of comprehensive genomic profiling assays to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies, immunotherapies 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 comprehensive genomic profiling, including FoundationOne, to identify genomic alterations, approved therapies or therapies in clinical trials and to estimate tumor mutational burden; the ability of tumor mutational burden to predict the likelihood or longevity of response to immunotherapies by patients with certain types of cancer; the ability of FoundationOne to inform therapeutic choices and improve patient outcomes; and the relevance of tumor mutational burden and comprehensive genomic profiling in oncology clinical care, including the ability to increase efficiencies in clinical care. 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 risk that the results presented are found to lack scientific, medical or clinical utility or that subsequent research renders the results presented less useful or not useful in clinical practice; Foundation Medicine's services and molecular information platform will not be able to identify genomic alterations or tumor mutational burden 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, 2015, which is on file with the Securities and Exchange Commission, as well as other risks detailed in 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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