September 8, 2017

Foundation Medicine to Present Validation Data for Its Assay Measuring Tumor Mutational Burden in Blood (bTMB), a New, Non-Invasive Predictor of Response to Immunotherapy

--Data Supports Inclusion of the bTMB Assay into a Phase III Clinical Trial of Atezolizumab Immunotherapy in Individuals with Advanced Lung Cancer--

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced presentations at the European Society for Medical Oncology (ESMO) Annual Meeting highlighting validation data for its novel assay to measure tumor mutational burden from blood (bTMB). These presentations will highlight retrospective data analysis from Roche/Genentech's Phase II POPLAR and Phase III OAK studies that enabled analytic and clinical validation for the bTMB assay. The studies demonstrate that high bTMB as measured by Foundation Medicine's assay is associated with response to atezolizumab in individuals with previously-treated non-small cell lung cancer (NSCLC), potentially offering a new option to expand personalized care options for patients with advanced cancer.

Based on these findings, Foundation Medicine also announced today that its bTMB assay will be integrated as part of Roche/Genentech's prospective, randomized Phase III Blood First Assay Screening Trial (BFAST) as a companion diagnostic assay to investigate bTMB as a non-invasive biomarker of response to first-line atezolizumab in advanced NSCLC patients.

"Foundation Medicine has previously shown that measuring tumor mutational burden from tissue samples can help reliably predict responses to immunotherapies. However, a critical need exists for measuring TMB via a non-invasive solution for cancer patients for whom tissue is not available or when a biopsy is not feasible," said Vincent Miller, M.D., chief medical officer at Foundation Medicine. "Our data at ESMO provide the first evidence that response to immunotherapy can be predicted using only a blood sample and we're pleased that we recently received FDA clinical trial approval for the Phase III study to validate bTMB as a biomarker in first-line immunotherapy. Based on the study results, we expect further development of our bTMB assay as a companion diagnostic, providing an important predictive and complementary solution to FoundationACT® liquid biopsy, and ultimately enabling physicians to make informed selection of targeted or immunotherapy treatments in the absence of tissue."

In the studies presented at ESMO, Foundation Medicine's bTMB assay was analytically validated to determine TMB with high precision and accuracy from as little as one percent tumor content in a blood sample. The assay was used to retrospectively analyze a total of 794 plasma samples from the Phase II POPLAR and Phase III OAK clinical trials. The analysis showed that atezolizumab demonstrated a clear benefit for overall survival. Additionally, there was a correlation between patients with high bTMB in those studies and longer progression-free survival (PFS) when treated with atezolizumab. In addition, bTMB was not found to correlate with PD-L1 expression levels as measured by tissue-based immunohistochemistry, suggesting that bTMB, like tissue TMB, provides independent and critical predictive information in addition to the information furnished by PD-L1 testing.

The bTMB assay validation presentations will take place during the following times:

Abstract #1295O -- Blood-based biomarkers for cancer immunotherapy: Tumor mutational burden in blood (bTMB) is associated with improved atezolizumab (atezo) efficacy in 2L+ NSCLC (POPLAR and OAK), Sept 8, 4:00pm - 5:30pm, Madrid Auditorium (Oral Presentation)

Abstract #102P -- Analytic validation of a next generation sequencing assay to identify tumor mutational burden from blood (bTMB) to support investigation of an anti-PD-L1 agent, atezolizumab, in a first line non-small cell lung cancer trial (BFAST), Sept 11, 1:15pm - 2:15pm, Hall 8 (Poster Presentation)

In totality, the company and its collaborators will present a total of 19 studies at the ESMO Annual Meeting, including three oral presentations, seven poster discussions and nine posters, which support the integration of comprehensive genomic profiling (CGP) and biomarkers such as tissue- and blood-based TMB to help guide personalized cancer care. These new data include insights into the landscape of tissue-based TMB across various types of cancer, which may help further stratify molecular subtypes of disease and guide more personalized treatment. Results will be presented from a study of more than 80,000 solid tumors, a study of more than 22,000 gastrointestinal cancers and a study of more than 2,000 melanoma cases (the largest known cohort of metastatic melanoma cases with comprehensive genomic profiling released to date). Together these results reveal pan-tumor and disease-specific alterations that may inform rational selection of immunotherapy.

Furthermore, new studies show the prevalence of TMB in subtypes of certain cancers where immunotherapy is not often considered, such as breast and thymic cancers. These findings may help expand the utility of TMB into new indications.

The European Society for Medical Oncology Annual Meeting will be held from September 8-12, 2017 in Madrid, Spain.

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 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 for Foundation Medicine

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 tissue and blood based TMB to predict responses to certain types of cancer, including NSCLC; the validation of bTMB as a biomarker in first-line immunotherapy; the development of bTMB as a companion diagnostic assay, the correlation of improvement in PFS for patients with NSCLC who have high bTMB treated with atezolizumab; the ability of CGP to improve patient outcomes; and the continuation of the Roche/Genentech BFAST trial and the subsequent reporting of data from the BFAST trial. 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 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, 2016, 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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