June 6, 2016

New Data from Foundation Medicine and Collaborators Supports Use of Comprehensive Genomic Profiling to Inform Therapeutic Choices in Advanced Breast Cancer

Genomic Information Revealed by FoundationOne® Leads to 41% Physician-Directed Change in Therapeutic Treatment Selection

Biomarkers of Immune Checkpoint Inhibitors Identify Opportunity for Clinical Response to Immunotherapies

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today presented new data in two presentations at the American Society of Clinical Oncology (ASCO) Annual Meeting 2016 that underscore the critical importance of integrating comprehensive genomic profiling into clinical care programs for the treatment of advanced breast cancer. Data presented from two separate studies showed:

- Molecular information elucidated from FoundationOne led physicians to change their recommended course of therapy for 41 percent of patient cases;
- 77 percent of patients profiled with FoundationOne harbored an alteration matched to an FDA-approved therapy;
- 98 percent of patients with advanced breast cancer had genomic alterations that matched therapeutics being studied in clinical trials; and
- 20 percent of advanced breast cancers possess high tumor mutational burden, suggesting a potential role for FoundationOne as a predictive biomarker for immune checkpoint inhibition.

"It's no longer sufficient to classify or treat breast cancer as a single disease, and we must continue to acknowledge and understand its vast, complex genomic variability in order to provide individuals with every opportunity for improved outcomes," said Vincent Miller, M.D., chief medical officer, Foundation Medicine. "In a striking example of the importance of genomic information in breast cancer treatment, data presented at ASCO show that comprehensive genomic profiling led to physician-recommended therapy changes, matches with FDA-approved therapeutic agents that otherwise may have been overlooked or missed, and links to clinical trials for investigational targeted agents. This data is significant for the approximately 40,000 individuals in the United States who present with metastatic breast cancer annually, and it underscores opportunity with precision medicine to improve outcomes by matching patients with the right therapies."

Key Data Highlights:

The poster "Decision impact analysis of comprehensive genomic profiling (CGP) in advanced breast cancer: A prospective study," presented by Raquel E. Reinbolt, M.D., assistant professor, internal medicine, college of medicine, The Ohio State University, presented data that demonstrated that comprehensive genomic profiling in advanced breast cancer provides therapy or clinical trial recommendations for more than 70 percent of patients screened. A prospective, single center, single arm study enrolled advanced breast cancer patients who were within 10 weeks of starting therapy and who had an estimated survival of ≥ 3 months. Key findings include:

- Comprehensive genomic profiling noted the existence of an FDA approved drug for 77 of 83 patients, with everolimus (n=72), temsirolimus (n=70), ponatinib (n=23) and pazopanib (n=20) being the most frequently selected by physicians
- At least one clinical trial was identified for 98 percent of patients
- A change in therapy was recommended by the treating physician for 34 of 83 patients (41 percent), and of these, 17 patients (50 percent) pursued the suggested treatment

A second poster "Biomarkers of Immune Checkpoint Inhibitor Response in Metastatic Breast Cancer: PD-L1 Protein Expression, PD-L1 Gene Amplification and Total Mutational Burden," presented by Jeffrey S. Ross, M.D., medical director, Foundation Medicine and Chair of the Department of Pathology, Albany Medical College, studied potential predictive biomarkers for immune checkpoint inhibitors in more than 6,000 breast cancer tumor samples at Foundation Medicine, and 84 breast cancer cases at Albany Medical Center. In the study, comprehensive genomic profiling using FoundationOne was performed on a cohort of 6,751 metastatic breast cancer tumor samples which were also evaluated for tumor mutational burden. PD-L1 expression detected by immunohistochemistry was used to predict patient survival in the 84 case Albany Medical Center cohort.

Key findings include:

- PD-L1 protein expression in infiltrating immunocytes was found to be a significant favorable prognostic factor, which significantly correlated with increased overall survival whereas lack of PD-L1 staining in both tumor cells and immunocytes was a significant adverse prognostic factor associated with decreased patient survival
- PD-L1 gene amplification was identified in only 57 of 6,751 (0.1 percent) metastatic breast cancer tumor samples, correlating with the potential for response to immune checkpoint inhibitors
- High tumor mutational burden was found in 1,351 of 6,643 (20 percent) metastatic breast cancer cases underscoring the potential for further studies measuring tumor mutational burden with FoundationOne to identify breast cancer patients as candidates for immunotherapy

Breast cancer is the most common type of cancer among women in the United States, excluding non-melanoma cancers of the skin. The American Cancer Society estimates that approximately 246,660 women will be diagnosed with breast cancer in 2016[1]. Although the majority of these patients will be cured of their disease in the primary treatment setting, the more than 40,000 cases of relapsed and metastatic breast cancer make this disease the second leading cause of death from cancer in American women[2]. The matching of patients with advanced breast cancer to personalized therapies holds significant promise to improving clinical outcomes for these patients.

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; the ability of FoundationOne to inform therapeutic choices in advanced breast cancers, including leading to physician-directed therapy changes and to improve patient outcomes; the relevance of comprehensive genomic profiling in oncology clinical care; and the ability of certain identified criteria in predicting potential response to certain therapies. 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, 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.

[1] American Cancer Society, Breast Cancer Key Statistics 2016

[2] American Cancer Society, Breast Cancer Key Statistics 2016

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Source: Foundation Medicine, Inc.