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Foundation Medicine to Present Validation for FoundationOne CDx™, a Comprehensive Genomic Profiling Assay for Advancing Precision Cancer Care

-- Data demonstrated high concordance between FoundationOne CDx and multiple FDA-approved companion diagnostics across five solid tumor cancer types, providing the capability to predict response for up to 15 targeted therapies --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Foundation Medicine, Inc.](#) (NASDAQ:FMI) today announced that the company will present validation data for FoundationOne CDx, its comprehensive genomic profiling assay, at the International Association for the Study of Lung Cancer (IASLC) 18th World Conference on Lung Cancer (WCLC). Data demonstrated high concordance with multiple companion diagnostics and other single marker assays currently used to match targeted therapies to people with certain types of non-small cell lung cancer (NSCLC), melanoma, colorectal cancer, ovarian cancer or breast cancer. The availability of a comprehensive genomic profiling assay that is concordant with multiple companion diagnostics has the potential to advance personalized healthcare for all constituents by providing biopharma companies a platform for accelerated drug development and by improving efficient access to targeted therapies for patients.

FoundationOne CDx is a comprehensive genomic profiling (CGP) assay that incorporates multiple companion diagnostics in a single platform with molecular profiling of the 320+ genes known to drive cancer growth. These validation data are also included in the Premarket Approval Application (PMA) for FoundationOne CDx which is currently under review by the U.S. Food and Drug Administration (FDA) and also by the Centers for Medicare & Medicaid Services (CMS) as part of their Parallel Review program for breakthrough devices. FoundationOne CDx is not commercially available at this time.

"The landscape of targeted cancer treatments and associated companion diagnostics has grown tremendously in recent years. However, the ability to match tumor-specific molecular information to appropriate treatments is limited by single gene and hot spot panel tests that can exhaust valuable time and tissue," said Vincent Miller, M.D., chief medical officer at Foundation Medicine. "We are excited by our data that demonstrate high concordance between FoundationOne CDx and seven FDA-approved companion diagnostics. The biomarkers confirmed through clinical concordance studies collectively are indicated for use for up to 15 targeted therapies across multiple tumor types, including lung cancer. A single, comprehensive, pan-cancer profiling assay that is concordant with multiple companion diagnostic assays, has the potential to provide significant benefits to patients and physicians, and to accelerate the development of new personalized treatments."

Results showed that FoundationOne CDx detected alterations in the *EGFR*, *ALK*, *BRAF*, *ERBB2*, *KRAS* and *BRCA1/2* genes and demonstrated concordance with FDA-approved companion diagnostics currently used to match targeted therapies to patients with certain types of non-small cell lung cancer (NSCLC), melanoma, colorectal cancer, ovarian cancer or breast cancer. In each of the separate studies, concordance was measured as positive percent agreement (PPA) with other FDA-approved tests.

The presentations will take place at the following times:

P2.02-052 -- A clinically-validated universal companion diagnostic platform for cancer patient care, Oct 17, 9:30am-4:00pm JST, Exhibit Hall (Poster Presentation)

P3.02-061 -- An *ALK* follow-on companion diagnostic using CGP for clinical care of patients with NSCLC, Oct 18, 9:30am-4:00pm JST, Exhibit Hall (Poster Presentation)

P3.02-062 -- An *EGFR* follow-on companion diagnostic for clinical care of patients with NSCLC, Oct 18, 9:30am-4:00pm JST, Exhibit Hall (Poster Presentation)

Foundation Medicine and its collaborators will make a total of nine presentations at the meeting, including two oral presentations, three mini-oral presentations and four posters which support the ability of CGP to guide more informed and personalized care in lung cancer. In addition to the FoundationOne CDx concordance data, new data will also include characterization of genomic alterations which may be associated with response or resistance to certain targeted treatments or immunotherapy, such as *MET* amplifications or alterations in *PTCH1* or *STK11* genes. Together these findings provide new insights into the genomic drivers of lung cancer to guide more precise treatment and support the use of CGP in clinical

care.

The IASLC 18th WCLC is being held October 15-18 in Yokohama, Japan.

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).

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

About the WCLC

The World Conference on Lung Cancer is the world's largest meeting dedicated to lung cancer and other thoracic malignancies, attracting over 6,000 researchers, physicians and specialists from more than 100 countries. The goal is to disseminate the latest scientific achievements; increase awareness, collaboration and understanding of lung cancer; and to help participants implement the latest developments across the globe. For more information, visit <http://wclc2017.iaslc.org/>.

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 FoundationOne CDx to enhance patient access to targeted therapies and clinical trials; the ability of CGP to improve patient outcomes; and the scope and timing of any approval of FoundationOne CDx as a medical device by the FDA and any coverage decision by CMS. 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 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; the FDA does not approve FoundationOne CDx as a medical device or that CMS does not decide to offer FoundationOne CDx as a covered benefit under Medicare; 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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