December 19, 2016

Foundation Medicine Receives FDA Approval of FoundationFocus™ CDxBRCA as a Companion Diagnostic for Rubraca™ (rucaparib) for the Treatment of Women with Ovarian Cancer

--First and only companion diagnostic to detect tumor BRCA1/2 alterations, potentially increasing the number of women who are eligible for Rubraca (rucaparib) therapy--

--FDA approval of FoundationFocus CDx$_{BRCA}$ marks important progress towards Foundation Medicine's development of a comprehensive universal companion diagnostic assay across multiple tumor types to advance precision medicine in oncology--

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ:FMI) today announced that the U.S. Food and Drug Administration (FDA) has approved FoundationFocus™ CDx$_{BRCA}$ for use as a companion diagnostic to aid in identifying women with ovarian cancer for whom treatment with Rubraca™ (rucaparib), a therapy developed by Clovis Oncology, Inc., is being considered. FoundationFocus CDx$_{BRCA}$ is an FDA-approved tissue-based, genomic assay that uniquely detects tumor *BRCA1* and *BRCA2* mutations (may include both germline (inherited) and somatic (acquired)) in ovarian cancer. FoundationFocus CDx$_{BRCA}$ may help identify more women who could benefit from Rubraca therapy as compared to conventional testing methods that only identify germline *BRCA1/2* mutations. Germline-only *BRCA1/2* testing identifies approximately half of all *BRCA1/2* mutations.[i,ii]

Rubraca is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the treatment of patients with deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca.

"These simultaneous approvals by the FDA represent a step forward for women with advanced ovarian cancer, an area where there is a tremendous need for effective therapeutic approaches and efficient ways to identify those most likely to respond to PARP inhibitor therapy," said Michael Pellini, M.D., chief executive officer of Foundation Medicine. "This approval also represents a significant milestone for Foundation Medicine, one that underscores the quality and value of our molecular information solutions to inform patient care and to accelerate and streamline the therapeutic development programs of our biopharmaceutical partners."

Foundation Medicine and Clovis Oncology closely collaborated on a regulatory strategy to develop FoundationFocus CDx$_{BRCA}$ in parallel with the development of Rubraca. Tissue samples taken from individuals with ovarian cancer who enrolled in rucaparib clinical trials were analyzed by Foundation Medicine utilizing comprehensive genomic profiling (CGP) to identify biomarkers associated with a response to therapy. These molecular signatures of response informed the development of FoundationFocus CDx$_{BRCA}$, which was utilized in Clovis' pivotal trial, ARIEL2, to identify patients and accelerate recruitment into the study. The companies filed concurrent pre-market approval (PMA) and new drug application (NDA) submissions with the FDA earlier this year.

With this FDA approval, FoundationFocus CDx$_{BRCA}$ is the first validated, tissue-based assay developed from the Quality Systems Regulations (QSR)-compliant version of Foundation Medicine's CGP assay, providing uniform analysis of all *BRCA1/2* coding exons.

Dr. Pellini continued, "FDA approval of our first companion diagnostic assay also represents an important advance in our efforts to utilize our rigorously validated CGP approach to deliver a universal companion diagnostic assay. We believe this approach may enable the efficient delivery of personalized cancer care by eliminating the guesswork for physicians through a comprehensive view of companion diagnostic claims, as well as potential treatment options based on guidelines, peer reviewed literature and clinical trials."

As part of the company's effort to develop a universal companion diagnostic, earlier this year, Foundation Medicine announced that FoundationOne®, the company's CGP assay for solid tumors, was accepted by the FDA and the Centers for Medicare and Medicaid Services (CMS) for Parallel Review. The FDA also granted Foundation Medicine's request for

review as part of its Expedited Access Pathway for breakthrough devices. If approved, FoundationOne would be an FDA-approved CGP assay that incorporates multiple companion diagnostics to support precision medicine in oncology, including an indication for use as a companion diagnostic across a diverse range of solid tumors, which is anticipated to include ovarian cancer.

More than 22,000 women will potentially be diagnosed with ovarian cancer in the U.S. during 2016.[iii] Ovarian cancer is the leading cause of female gynecologic cancer-related deaths[iv] and one in four women with ovarian cancer have a germline or somatic *BRCA* mutation.[ii]

About FoundationFocus CDx$_{BRCA}$

Intended Use: FoundationFocus CDx$_{BRCA}$ is a next generation sequencing test for qualitative detection of *BRCA1* and *BRCA2 (BRCA1/2)* alterations in formalin-fixed paraffin-embedded (FFPE) ovarian tumor tissue. The FoundationFocus CDx$_{BRCA}$ assay detects sequence alterations in *BRCA1/2* genes. Results of the test are used as an aid in identifying ovarian cancer patients for whom treatment with Rubraca™ (rucaparib) is being considered. If a patient is positive for any of the deleterious alterations specified in the *BRCA1/2* classification, the patient may be eligible for treatment with Rubraca. This assay is to be performed at Foundation Medicine, Inc., a single laboratory site located at 150 Second Street, Cambridge, MA 02141. For more information about FoundationFocus CDx$_{BRCA}$ assay, visit http://www.foundationmedicine.com/focus.

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 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 any benefits of FoundationFocusCDx$_{BRCA}$ for women with advanced ovarian cancer; the ability of FoundationFocusCDx$_{BRCA}$ to identify more women who could benefit from PARP inhibitor therapy as compared to conventional testing methods that only identify germline BRCA1/2 mutations; the scope and timing of any approval of FoundationOne as a medical device by the FDA, and the inclusion of a companion diagnostic for ovarian cancer; the scope and timing for a coverage decision by CMS for FoundationOne; and the ability of FoundationFocusCDx$_{BRCA}$ to enable an efficient and personalized approach to cancer 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 risks that FoundationFocusCDx$_{BRCA}$ will not identify up to twice as many women who could benefit from PARP inhibitor therapy over germline-only conventional testing methods; the FDA will approve other validated, tissue-based assays that provide uniform analysis of all BRCA 1/2 coding exons; Foundation Medicine is not able to make FoundationFocusCDx$_{BRCA}$ accessible to physicians and patients due to commercial and financial obstacles; FDA does not approve FoundationOne as a medical device or CMS does not cover FoundationOne under the Medicare reimbursement program; in conducting the parallel review of FoundationOne, either the FDA or CMS is delayed in the completion of its review; 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 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.

[i] Hennessy BTJ, et al. Somatic mutations in BRCA1 and BRCA2 could expand the number of patients that benefit from poly (ADP ribose) polymerase inhibitors in ovarian cancer. *JCO.* 2010;28(22):3570-6.

[ii] Pennington KP, et al. Germline and somatic mutations in homologous recombination genes predict platinum response and survival in ovarian, fallopian tube, and peritoneal carcinomas. *Clin Cancer Res*. 2013;20(3):764-75.

[iii] American Cancer Society. 2016, February 4. Overview of ovarian cancer. Retrieved from http://www.cancer.org/cancer/ovariancancer/detailedguide/ovarian-cancer-key-statistics.

[iv] Ovarian Research Fund Alliance. (n.d.) Statistics. Retrieved from https://ocrfa.org/patients/about-ovarian-cancer/statistics/.

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