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Foundation Medicine and Clovis Oncology Expand Collaboration to Develop Novel Companion Diagnostic for Rucaparib in Ovarian Cancer

Companion diagnostic development builds upon regulatory strategy for Foundation Medicine's comprehensive genomic profiling platform and differentiated clinical development strategy for Clovis Oncology

CAMBRIDGE, Mass. & BOULDER, Colo.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ: FMI) and Clovis Oncology, Inc. (NASDAQ: CLVS) today announced the expansion of their ongoing collaboration to incorporate a coordinated regulatory strategy for the development of a novel Premarket Approval (PMA) companion diagnostic test. This test is designed for use by physicians to identify patients most likely to respond to rucaparib, Clovis' poly (ADP-ribose) polymerase (PARP) inhibitor currently the subject of Phase 2 and Phase 3 clinical trials in patients with ovarian cancer.

This companion diagnostic is being developed in parallel with the clinical development of rucaparib to facilitate an FDA submission of the PMA for the companion diagnostic concurrent with the New Drug Application (NDA) for rucaparib. Foundation Medicine's platform, upon which the companion diagnostic will be based, is currently in use in Clovis' ongoing ARIEL2 clinical study of rucaparib in patients with ovarian cancer. The test assesses multiple cancer-related genes as well as all classes of genomic alterations, and it utilizes advanced algorithms based on Foundation Medicine's molecular information platform.

"Patient selection is a key aspect of our development and regulatory strategy for rucaparib. Ovarian cancer patients often present with a molecular signature of DNA repair deficiencies beyond germ-line BRCA that cannot be characterized by the conventional diagnostic tests available today," said Patrick J. Mahaffy, president and CEO of Clovis Oncology. "We are pleased to advance our collaboration with Foundation Medicine and utilize their unique genomic profiling platform and expertise to identify patients most likely to benefit from rucaparib."

Since 2012, Foundation Medicine has been conducting comprehensive genomic profiling to analyze tissue samples from ovarian cancer patients enrolled in rucaparib clinical trials in order to identify biomarkers associated with response. Initial findings identified the molecular signatures of likely responders, and the companies are now working together to incorporate the genomic signature into a companion diagnostic test. Under the terms of the expanded agreement, Foundation Medicine will build a dedicated laboratory to support the development and FDA-approval of the companion diagnostic test and will receive milestone payments for its successful development and registration.

"In addition to helping bring an important new therapy to patients with ovarian cancer, this collaboration marks a paradigm shift in the development of companion diagnostics. The use of Foundation Medicine's platform is an important step in the evolution of cancer care from a static, single-gene companion diagnostic approach toward a universal companion diagnostic standard," said Michael J. Pellini, M.D., president and CEO of Foundation Medicine. "This agreement complements Foundation Medicine's plans to develop an FDA-approved companion diagnostic and supports our overall strategy to work with the FDA to establish the appropriate regulatory framework for novel, comprehensive genomic profiling platforms. We are very pleased to continue our support of Clovis' highly differentiated clinical development program and maintain our efforts with the company to identify the ovarian cancer patients most likely to benefit from rucaparib."

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's clinical assays, FoundationOne™ for solid tumors and FoundationOne™ Heme for hematologic malignancie sarcomas and pediatric cancers, each provide a fully informative genomic profile to identify the molecular alterations in a patient's tumor and match them with relevant targeted therapies 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 www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-

cancer agents in the U.S., Europe and additional international markets. Clovis Oncology targets development programs at specific subsets of cancer populations, and simultaneously develops diagnostic tools that direct a compound in development to the population that is most likely to benefit from its use. Clovis Oncology is headquartered in Boulder, Colorado.

Foundation Medicine 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 a collaboration between Foundation Medicine and Clovis Oncology, the development by Clovis Oncology of a therapeutic product for ovarian cancer, the development by Foundation Medicine of a companion diagnostic test, the creation by Foundation Medicine of a dedicated laboratory to support the companion diagnostic test, and the development of a regulatory framework for the FDA approval of comprehensive genomic diagnostic tests. 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 that Clovis Oncology may not successfully develop or obtain regulatory approvals for rucaparib for treatment of ovarian cancer; that Foundation Medicine may not successfully develop or obtain regulatory approvals for a companion diagnostic test for rucaparib; that rucaparib and the Foundation Medicine companion diagnostic test may not be launched or subsequently achieve successful commercial acceptance; that the FDA may not support the establishment of a regulatory framework for approving comprehensive genomic profiling platforms; 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, 2013, 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.

Clovis Oncology Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Clovis Oncology, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks and uncertainties that could cause Clovis Oncology's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical development program for rucaparib, the corresponding development pathways of its companion diagnostic, actions by regulatory authorities regarding whether to approve drug applications that may be filed, as well as their decisions regarding drug labeling, and other matters that could affect the availability or commercial potential of rucaparib or its companion diagnostic, including competitive developments. Clovis Oncology does not undertake to update or revise any forward-looking statements. A further description of risks and uncertainties can be found in Clovis Oncology's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its reports on Form 10-Q and Form 8-K.

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