May 12, 2014

Foundation Medicine Announces Key Developments in International Commercialization Efforts

Company Receives CE Mark Approval for FoundationOne®, Adds New Distribution Partner and Appoints Experienced Executive to Lead International Expansion

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Foundation Medicine, Inc. (NASDAQ: FMI) today announced that it has obtained a CE mark for FoundationOne®. The CE mark allows FoundationOne to be placed on the market in the European Economic Area. In addition, Foundation Medicine has added to its growing global business partners by establishing a partnership with Barcelona, Spain-based Laboratorios LETI for the distribution of the company's clinical products to physicians in Spain and Portugal. The company anticipates this partnership will serve as a model for similar commercial relationships with leading distributors in select markets around the world.

Foundation Medicine also announced the appointment of Urmi Prasad Richardson as vice president, international to lead its ongoing international commercialization efforts. Ms. Richardson brings more than 15 years of global experience developing and executing commercialization plans and strategic operations, specializing in molecular diagnostics and medical devices. Prior to joining Foundation Medicine, Ms. Richardson held leadership positions at Chiron, Novartis and Immucor. Ms. Richardson will be based in Germany.

"To date, we have reported clinical tests to customers in more than 40 countries outside of the United States, and with the addition of Urmi and other professionals to our commercial team, we are poised to further develop our international strategy and continue to grow our global business to support the increasing demand for our clinical products," said Kevin Krenitsky, M.D., chief commercial officer and senior vice president of international strategy, Foundation Medicine. "We are very pleased to have received a CE Mark and look forward to expanding the availability and adoption of FoundationOne to customers in the European oncology community."

The company's clinical assays, FoundationOne for solid tumors and FoundationOne Heme for hematologic malignancies, sarcomas and pediatric cancers, provide a fully informative genomic profile to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies and clinical trials. Foundation Medicine has not yet filed an application for a CE Mark for FoundationOne Heme.

As part of Foundation Medicine's ongoing international collaborations, FoundationOne is also being used for comprehensive genomic profiling in the WINTHER trial, an ongoing clinical trial to provide biology-oriented targeted therapies to patients with advanced solid tumors. The trial was initiated by the internationally renowned WIN Consortium in personalized cancer medicine, of which Foundation Medicine is a member.

"Cancer care is undergoing a paradigm shift in which each patient's treatment options can be informed by the molecular alterations driving a patient's tumor," said Jean-Charles Soria, M.D., Ph.D., professor of medicine and medical oncology at South-Paris University; chairman, Drug Development Department, Gustave Roussy Cancer Campus; and principal investigator of the WINTHER trial. "With more and more targeted cancer therapies becoming available, physicians need access to comprehensive genomic profiling in clinical care to evaluate the best treatment options or clinical trials for each patient."

For more information, or to order FoundationOne or FoundationOne Heme, please visit www.FoundationOne.com.

About FoundationOne®

FoundationOne, the company's first clinical product, is a fully informative genomic profile for solid tumors used by oncologists to identify the molecular alterations in a patient's tumor and match those alterations with relevant targeted therapies and clinical trials. Using next-generation sequencing in routine cancer specimens, FoundationOne interrogates all genes somatically altered in human cancers that are validated targets for therapy or unambiguous drivers of oncogenesis based on current knowledge. It reveals all classes of genomic alterations including base substitutions, insertions, deletions, copy number alterations and select rearrangements. FoundationOne fits easily into the clinical workflow of the ordering physician, and test results are provided in an easy-to-interpret report supported by a comprehensive review of published literature. FoundationOne is a laboratory-developed test performed at Foundation Medicine's CLIA-certified lab. Please visit www.FoundationOne.com for more information.

About FoundationOne® Heme

FoundationOne Heme is a fully informative genomic profile for hematologic cancers (leukemia, lymphoma and myeloma), sarcomas and pediatric cancers, designed to provide physicians with clinically actionable information to guide treatment options for patients based on the genomic profile of their cancer. It is Foundation Medicine's second clinical product and was developed in collaboration with Memorial Sloan-Kettering Cancer Center. Using next-generation sequencing in routine cancer specimens, FoundationOne Heme interrogates all genes somatically altered in these cancers that are validated targets for therapy or unambiguous drivers of oncogenesis based on current knowledge. The test employs RNA sequencing in addition to DNA sequencing to simultaneously detect all classes of genomic alterations, including base pair substitutions, insertions and deletions, copy number alterations and rearrangements, and gene fusions (a type of alteration that is a common driver of hematologic malignancies, sarcomas and pediatric cancers). FoundationOne Heme fits easily into the clinical workflow of the ordering physician, and test results are provided in an easy-to-interpret report supported by a comprehensive review of published literature. FoundationOne Heme is a laboratory-developed test performed at Foundation Medicine's CLIA-certified lab. Please visit www.FoundationOne.com for more information.

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 malignancies, sarcomas and pediatric cancers, provide a fully informative genomic profile to identify the molecular alterations in a patient's cancer 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).

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 company's satisfaction of marketing requirements in the European Union for FoundationOne; an increase in the number of commercial relationships by the company with distributors for the distribution of the company's products; the continued leadership by Ms. Urmi Richardson of the company's international commercialization efforts; the increased adoption of FoundationOne by customers in Europe and other areas outside the United States, and the ability of commercial partnerships to accelerate this growth outside the United States; the development of the company's international strategy; the success of, and the company's continued participation in, the WINTHER trial; and the continued growth of the company's global business. 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 marketing requirements in the European Union applicable to the company's products may change; that partners for commercial relationships may not be able to offer, or be interested in offering, the company's products; that Ms. Richardson may not be available to represent the company; that the WINTHER trial continues in accordance with the trial design; that FoundationOne or FoundationOne Heme and any subsequent products may not achieve sustained and significant commercial adoption; that the company's expectations and beliefs regarding the future conduct and growth of Foundation Medicine's business and the markets in which we operate may not materialize; that delays or denials in obtaining coverage and reimbursement decisions for FoundationOne, FoundationOne Heme and subsequent products may not occur; that the company may not achieve profitability, may not compete successfully, may not manage its growth, or may not develop its molecular information platform; and that 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 Quarterly Reports on Form 10‑Q and any subsequent filings with the Securities and Exchange Commission, may be realized. 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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Source: Foundation Medicine, Inc.