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Foundation Medicine and AstraZeneca Collaborate to Develop Companion Diagnostic Assays in Oncology

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Foundation Medicine, Inc.](#) (NASDAQ:FMI) today announced an agreement with AstraZeneca to develop companion diagnostic assays to facilitate personalized medicine in oncology by identifying patients most likely to benefit from medicines within AstraZeneca's oncology pipeline.

"We use companion diagnostics throughout clinical development to deliver innovative, targeted therapies to patients most likely to benefit," said Ruth March, VP and Head of Personalised Healthcare & Biomarkers at AstraZeneca. "The leading genomic profiling approach provided by Foundation Medicine can help ensure that patients are matched with therapies specifically targeted to the molecular drivers of their disease."

As part of the collaboration agreement, AstraZeneca will utilize the Quality Systems Regulations (QSR)-compliant version of Foundation Medicine's comprehensive genomic profiling assay for solid tumors to enroll patients into clinical trials of therapies that target genomically driven mechanisms of disease. The companion diagnostic assay assesses multiple cancer-related genes as well as all four classes of genomic alterations, and will be developed in parallel with the clinical development of AstraZeneca medicines as part of a coordinated regulatory strategy.

"We're delighted to expand our relationship with AstraZeneca to now include the development of companion diagnostics for their novel anti-cancer medicines," said Steven J. Kafka, Ph.D., President and Chief Operating Officer for Foundation Medicine. "This collaboration agreement, the fourth we have put in place with leading oncology companies, underscores the importance and potential of utilizing our rigorously validated, comprehensive profiling approach to make available to physicians an FDA-approved universal companion diagnostic solution for use with targeted medicines. We look forward to providing further updates as individual programs are initiated."

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 and sarcomas, provide a comprehensive 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 <http://www.FoundationMedicine.com> or follow Foundation Medicine on Twitter (@FoundationATCG).

About AstraZeneca in Oncology

AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least 6 new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, we are committed to advance New Oncology as one of AstraZeneca's six Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy, as illustrated by our investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms -- immuno-oncology, the genetic drivers of cancer and resistance, DNA damage response and antibody drug conjugates -- and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

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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 an agreement between Foundation Medicine and AstraZeneca to develop companion diagnostic assays to facilitate personalised medicine in oncology, the development of a coordinated regulatory strategy, the use by AstraZeneca of such assays to enroll patients into clinical trials of therapies that target the underlying genomic mechanisms of disease, and to make available to physicians an FDA-approved universal companion diagnostic solution for use with targeted medicines. 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 Foundation Medicine is not able to develop companion diagnostic assays that meet the requirements of AstraZeneca, the risk that AstraZeneca does not proceed with the development of therapies that target the underlying genomic mechanisms of disease, the risk that a coordinated regulatory strategy cannot be implemented, the risk that AstraZeneca determines to rely upon assays developed by other parties, 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.

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