# *Media Release*

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## FDA approves Foundation Medicine's FoundationOne CDx, the first pan-tumour comprehensive genomic profiling assay incorporating a broad range of companion diagnostics

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has approved FoundationOne CDx™, Foundation Medicine's comprehensive companion diagnostic assay for personalised oncology care[1]. FoundationOne CDx supports physicians in clinical decision-making by providing a report that describes the unique genomic profile of the patient's tumour as well as associated approved therapies and relevant clinical trial information. FDA approval of this assay, based on its clinical and analytical validation, now means the service can be used as a companion diagnostic for therapy selection when people have been diagnosed with solid tumours.

"The approval of FoundationOne CDx represents a major advance in the personalisation of cancer care, facilitating access for patients in the US to a comprehensive pan-tumour companion diagnostic that will help identify approved treatment options based on the molecular footprint of each individual's cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "Our belief is that profiling will increasingly become routine in clinical practice, so we have worked closely with Foundation Medicine to develop an extensive clinically and analytically validated platform that can support both existing and future companion diagnostic needs."

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FoundationOne CDx is the first FDA-approved pan-tumour comprehensive companion diagnostic assay to:

- assess all four classes of genomic alterations in 324 genes known to drive cancer growth, providing information to help guide the decisions of treating physicians;
- identify patients with advanced cancer who are likely to respond to targeted therapies, based on their individual genomic profile; and,
- report genomic signatures, including microsatellite instability (MSI) and tumour mutational burden (TMB), and report genomic alterations in other genes [relevant to other therapies] for use by physicians for patient management according to professional guidelines in oncology.

Of the 17 therapies currently approved for inclusion in the report, twelve are approved as first-line treatment options for their respective indications. The number of on-label targeted therapies in the report is expected to increase over time as Foundation Medicine and its partners gain FDA approval for additional biomarkers on the platform.

The approval of FoundationOne CDx also represents the first next generation sequencing (NGS)-based companion diagnostic for Alecensa® (alectinib), an FDA-approved monotherapy for the treatment of people with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)[2]. Alecensa is approved in both the front-line setting and for people who have progressed on or are intolerant to crizotinib. Including ALK-rearrangements in a larger comprehensive panel may ensure that more patients are identified and eligible for treatment based on their ALK-positive status.

Roche acquired a majority stake in Foundation Medicine in April 2015, and since then, has been actively commercialising Foundation Medicine's portfolio of services in countries outside the US, with more than 20 countries on three continents already having launched FoundationOne.

**About FoundationOne CDx**

FoundationOne CDx is a comprehensive genomic profiling service for solid tumours that provides potentially actionable information with the molecular profiling of 324 genes known to drive cancer growth. FoundationOne CDx is intended to be used as a comprehensive companion diagnostic for patients with certain types of NSCLC, melanoma, colorectal cancer, ovarian cancer or breast cancer to identify those patients that may benefit from treatment with one of 17 targeted therapies following the detection of alterations in the *EGFR, ALK, BRAF, ERBB2, KRAS, NRAS,* and *BRCA1/2* genes.

FoundationOne CDx is an NGS-based in vitro diagnostic for detection of base substitutions, insertion and deletion alterations (indels), copy number alterations (CNAs) and select gene rearrangements in 324 genes, as well as genomic signatures including MSI and TMB, using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumour tissue specimens. FoundationOne CDx is intended to be used by physicians as decision-making support in consideration of a patient's genomic profile for therapy selection and patient management according to professional guidelines in oncology for cancer patients.

**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).

**About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.



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**References**

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[2] FDA Highlights of Prescribing Information for Alecensa [Internet; cited 2017 December 1]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208434s003lbl.pdf