Roche announces FDA approval of FoundationOne Liquid CDx, a comprehensive pan-tumour liquid biopsy test

- **FoundationOne Liquid CDx analyses more than 300 cancer-related genes and multiple genomic signatures to help inform treatment decisions for all solid tumour cancers**
- **Using a simple blood draw, the test allows more patients with advanced cancer to benefit from the insights of comprehensive genomic profiling, for example when a tissue biopsy is not possible or recommended**
- **FoundationOne Liquid CDx adds to Foundation Medicine's genomic testing portfolio supporting Roche's mission to deliver truly personalised healthcare**
- **Roche is committed to improve patient outcomes by providing multiple testing options that support decision-making during all lines of therapy**
- **FoundationOne Liquid CDx is available to order, as of 28 August 2020, replacing Foundation Medicine's currently available liquid biopsy test FoundationOne Liquid**

Basel, 28 August 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved FoundationOne®Liquid CDx, Foundation Medicine's comprehensive pan-tumour liquid biopsy test for patients with solid tumours. FoundationOne Liquid CDx is a comprehensive genomic profiling (CGP) test that analyses more than 300 cancer-related genes and multiple genomic signatures to optimise patient care. Cancer is a disease of the genome, driven by genetic mutations within a tumour's DNA. CGP is used to identify these unique mutations to determine how a tumour behaves and grows, and these insights can help physicians to determine a personalised treatment plan for each individual patient based on the specific mutations identified.

As well as approving FoundationOne Liquid CDx as a CGP test for patients with any solid tumour, the FDA approved the test for use as a companion diagnostic to identify patients who may benefit from treatment with certain prostate and lung cancer therapies, including Rubraca® (rucaparib), a poly (ADP-ribose) polymerase (PARP) inhibitor for treatment in patients with BRCA 1/2-mutant metastatic castration-resistant prostate cancer, and three first-line tyrosine kinase (TKI) inhibitors for the treatment of patients with non-small cell lung cancer. By incorporating multiple genes, including several companion diagnostic biomarkers, the test can help save time versus sequential biomarker testing.

"Many cancer patients are unable to have a tissue biopsy. FoundationOne Liquid CDx may provide a minimally-invasive option for patients who otherwise might not have benefitted from comprehensive genomic profiling," said Levi Garraway, M.D., Ph.D., Roche's Executive Vice President, Chief Medical Officer, Head of Global Product Development and Co-Founder of Foundation Medicine Inc. "The convenience of testing a blood sample may also enable more rapid treatment decisions, so that patients can feel reassured they are not losing time to fight their disease."

FoundationOne Liquid CDx analyses circulating cell-free DNA from a patient's blood sample and uses

massively parallel sequencing to detect the four main classes of genomic alterations. The test is FDA-approved to report short variants in 311 genes including rearrangements and copy number losses in BRCA1 and BRCA2 genes. The results are delivered in an integrated report that identifies alterations matched to FDA-approved therapies. The report also delivers information about genomic signatures to help inform the use of other therapies including immunotherapies, and provides relevant clinical trial information.

“With the acceleration towards precision therapy approaches, it is important that physicians have the highest quality tools that can provide an accurate picture of their patients’ cancers in a timely manner,” said Fortunato Ciardiello, M.D., Ph.D, Professor of Medical Oncology, Director of the Division of Medical Oncology at the Università della Campania Luigi Vanvitelli, Italy. “With the approval of FoundationOne Liquid CDx physicians have the choice of two high-quality, FDA-approved comprehensive genomic profiling tests, enabling them to select the most optimal option for their patients.”

The FDA approval of FoundationOne Liquid CDx was based on analytical and clinical validation studies including more than 7,500 samples and 30,000 unique variants across more than 30 cancer types. Evaluation of the platform using multiple validation methods across a broad range of tumour types demonstrated high sensitivity and specificity, even at the low allele frequencies often observed in clinical blood samples [1,2].

FoundationOne Liquid CDx is the latest addition to Foundation Medicine’s portfolio of high-quality CGP tests and the second of the company’s CGP tests to receive FDA approval. FoundationOne®CDx, Foundation Medicine’s tissue-based genomic test for patients with solid tumours received FDA approval in 2017. Together, these high-quality genomic profiling tests offer physicians important options for detecting specific genomic alterations that help guide efficient, personalised treatment decisions, while reducing the time and sample needed when testing for multiple biomarkers one at a time. FoundationOne Liquid CDx can also provide complementary insights to tissue-based testing regarding tumour heterogeneity (the differences between cancer cells), and clonal evolution (how tumours evolve over time).

About FoundationOne®Liquid CDx
FoundationOne Liquid CDx is a qualitative next-generation sequencing based in vitro diagnostic test for prescription use only that uses targeted high throughput hybridisation-based capture technology to analyse 324 genes utilising circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of advanced cancer patients. The test is FDA-approved to report short variants in 311 genes, including rearrangements and copy number losses in BRCA1 and BRCA2, and is a companion diagnostic to identify patients who may benefit from treatment with specific targeted therapies (listed in Table 1 of the Intended Use) in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Patients who are negative for companion diagnostic mutations should be reflexed to tumour tissue testing and mutation status confirmed using an FDA-approved tumour tissue test, if available. For the complete label, including companion diagnostic indications and complete risk information, please visit www.F1LCDxLabel.com.

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. More than 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. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.

References

[1] Foundation Medicine Inc. Internal data on file. 95% limit of detection (median) of 0.40% variant allele fraction (VAF) for select substitutions and indels, 0.37% VAF for select rearrangements, 21.7% tumor fraction (TF) for copy number amplifications, and 30.4% TF for copy number losses.
[2] Foundation Medicine Inc. Internal data on file. 0% false positive rate for rearrangements and copy number alterations, 0.013% false positive rate for substitutions and indels

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