



For immediate release:

US-FDA Approved Foundation Medicine's FoundationOne®Liquid CDx, a Pan-Tumor Liquid Biopsy Genomic Test for Late Stage Cancer Patients now Available in India

- **FoundationOne®Liquid CDx is a comprehensive genomic profiling test** that analyses more than **300 cancer-related genes** and multiple genomic signatures from a single blood draw to help make informed treatment decisions for all solid tumor cancers

Mumbai, 18 November 2020: Roche Products (India) Pvt. Ltd. (Roche Pharma India) announces the launch of FoundationOne®Liquid CDx, Foundation Medicine's comprehensive pan-tumor liquid biopsy test for patients with solid tumors in India. US FDA approved the FoundationOne®Liquid CDx, a comprehensive genomic profiling (CGP) test on August 26. This is the first test that can analyze more than 300 genes and multiple genomic signatures to optimize patient care.

Cancer is a disease of the genome. Most tumors harbor a constellation of genomic alterations that may dictate their clinical behavior and treatment response. Blood-based biomarker testing options like FoundationOne®Liquid CDx can help expand access to genomic insights in patients with advanced cancer as compared to a tissue biopsy, which may not be an option for many patients due to reasons such as tumor location and patient's health status. FoundationOne®Liquid CDx is a single non-invasive test based on Next Generation Sequencing technology that gives access to genomic information of over 300 genes. Additionally, the report also provides information about the biomarker signatures microsatellite instability (MSI), and blood tumor mutational burden (bTMB) to support informed decision making for targeted and immunotherapies.

"Roche has always been committed to provide best-in-class solutions to serve the needs of cancer patients globally as well as in India. We believe that cancer patients in our country and their physicians deserve the highest quality genomic testing to guide personalized treatment decisions. We are delighted to make this test now available for Indian patients, post US-FDA approval." said **Mr. V. Simpson Emmanuel, Managing Director, Roche Pharma India.**

Elucidating the nature of the genomic alterations has led to an increase in discovery of many targeted therapy options for patients in recent years. It is becoming increasingly important to provide personalised treatment options to the patients as it has an unprecedented scope in changing the paradigm of cancer care in the future.

"US FDA approved FoundationOne®Liquid CDx is a comprehensive genomic profiling test that reports genomic alteration results of more than 300 genes, including genomic signatures such as blood tumor mutational burden (bTMB) and microsatellite instability (MSI), as well as all NTRK fusions for any solid tumor with a single blood draw. It will enable more rapid and informed treatment decisions at the point of care."* said **Dr. Bruno Jolain, Director - Medical, Roche Pharma India.**



FoundationOne®Liquid CDx is mainly prescribed in the metastatic cancers i.e. at stage IV of the disease. The test samples collected from the patients in India are sent to Foundation Medicine Inc.'s lab in Cambridge, MA, US where the test is performed. The patients are required to discuss with their treating physicians on their eligibility for this test.

The total disease burden of cancer in India is anticipated to increase significantly from about 1 million new cases in 2012 to more than 1.7 million per year by 2035. [1] With such an alarming trend, it is becoming increasingly important to shift towards new treatment approaches like personalized medicine.

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References:

[1] [Cancer burden and health systems in India 1 - The growing burden of cancer in India: epidemiology and social context](#)

**NTRK fusion - A mutation (change) that occurs when a piece of the chromosome containing a gene called NTRK breaks off and joins with a gene on another chromosome. NTRK gene fusions lead to abnormal proteins called TRK fusion proteins, which may cause cancer cells to grow. NTRK gene fusions may be found in some types of cancer, including cancers of the brain, head and neck, thyroid, soft tissue, lung, and colon. Also called neurotrophic tyrosine receptor kinase gene fusion. (<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/ntrk-gene-fusion>)*

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 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 tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if available. For the complete label, including companion diagnostic indications and complete risk information, please visit www.F1LCDxLabel.com.

About Foundation Medicine Inc. (FMI):

Foundation Medicine 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 and is based out of Cambridge, Massachusetts, USA. Roche: acquired Foundation medicine in 2019 and is a licensed distributor of Foundation Medicine's portfolio ExUS including India. For more information, please visit www.foundationmedicine.in.

About Roche Products (India) Pvt. Ltd.

Roche Products (India) Private Limited was incorporated in 1994 as a wholly owned subsidiary of the Roche Group, headquartered in Basel, Switzerland. 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.

For more than 60 years, Roche has been committed to making a difference to the lives of people in India. Today, Roche is the leader in oncology treatment in India; apart from cancer, Roche's has innovative medicines in other therapy areas too: transplantation, rheumatoid arthritis (RA), and chronic kidney disease (CKD)-related anaemia. Roche believes in making the latest and most innovative medicines accessible to patients in India in the fastest possible time.



For more than 50 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, Roche is investing more than ever in our effort to bring innovative treatment options that help a person's own immune system fight cancer.

For more information on Roche Pharma India, visit www.rocheindia.com.

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