FDA Approves Liquid Biopsy Test For Multiple Cancers and Biomarkers

The blood test identifies biomarkers that could make patients eligible for targeted therapies.

November 9, 2020 By Food and Drug Administration (FDA)

On October 26 and November 6, 2020, the Food and Drug Administration approved the liquid biopsy next-generation sequencing-based FoundationOne Liquid CDx test (Foundation Medicine, Inc.) as a companion diagnostic device for multiple additional biomarkers detected in cell free-DNA isolated from plasma specimens.

The companion diagnostic indications in the October 26 approval are

1) to identify mutations in BRCA1 and BRCA2 genes in patients with ovarian cancer eligible for treatment with rucaparib (RUBRACA, Clovis Oncology, Inc.),
2) to identify ALK rearrangements in patients with non-small cell lung cancer (NSCLC) eligible for treatment with alectinib (ALECENSA, Genentech USA, Inc). and
3) to identify mutations in the PIK3CA gene in patients with breast cancer eligible for treatment with alpelisib (PIQRAY, Novartis Pharmaceutical Corporation).

On November 6, FDA approved the FoundationOne Liquid CDx test as a companion diagnostic device to identify mutations in BRCA1, BRCA2 and ATM genes in patients with metastatic castration resistance prostate cancer (mCRPC) eligible for treatment with olaparib (LYNPARZA, AstraZeneca Pharmaceuticals LP).

FoundationOne Liquid CDx approval as a companion diagnostic for rucaparib, alpelisib, alectinib, and olaparib was based on the retrospective testing with FoundationOne Liquid CDx of available plasma samples from patients enrolled in four clinical trials that supported the approval of associated therapeutics. Efficacy for rucaparib, alpelisib, alectinib, and olaparib was shown to be maintained in patients with confirmed BRCA1 and/or BRCA2 gene alterations, PIK3CA mutations, ALK rearrangement, and BRCA1, BRCA2, and/or ATM gene alterations, respectively, by FoundationOne Liquid CDx. If the specific mutations and alterations associated with these approvals are not detected in the blood, then a tumor biopsy should be performed to determine if the specific mutations and alterations are present.

View the Summary of Safety and Effectiveness for the FoundationOne Liquid CDx test (P200006 and P200016).

The FoundationOne Liquid CDx test was granted Breakthrough Device designation, in which the FDA provides intensive interaction and guidance to the company on efficient device development.

A description of the FDA Breakthrough Device program can be found at Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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