FOUNDATION MEDICINE®

Foundation Findings: Publication Details

Genomic screening is key in identifying men who may benefit from treatment with RUBRACA® (rucaparib)[1]

TRITON2 evaluates the PARP inhibitor rucaparib for the treatment of men with mCRPC associated with a deleterious alteration in BRCA or other DDR gene who have progressed after next-generation AR-directed therapy and a taxane-based chemotherapy. The clinical trial screening assays for tumor testing were FoundationOne®CDx (tissue) and FoundationOne®Liquid (ctDNA). FoundationOne®Liquid CDx was used to demostrate clinical validity of the results.

TRITON2: A Multicenter, Open-label Phase 2 Study of Rucaparib in Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency.

APPROXIMATELY

12%

OF mCRPC PATIENTS HARBOR A DELETERIOUS *BRCA1/2* ALTERATION[1,2]

Such mutations are approximately 50% germline and 50% somatic.[1]

By testing for all *BRCA* mutations, regardless of germline or somatic*, our portfolio of tests can **identify more than twice as many men** who may benefit from RUBRACA® than conventional germline-only testing.[3]

* Foundation Medicine detects both somatic and germline alterations but does not differentiate between the two on reports.

115

PATIENTS

with a *BRCA* alteration with or without measurable disease **received FoundationOne Liquid**† testing as part of the safety and efficacy populations in the TRITON2 clinical trial. In order to show clinical efficacy, FoundationOne Liquid CDx was used later in the trial to demonstrate clinical validity.

† FoundationOne®Liquid is a previous version and different from FoundationOne®Liquid CDx. For concordance results between these two tests, please see our full label at *www.F1LCDxLabel.com.*

43.5%

Confirmed ORRs per independent radiology review. ORRs were similar for patients with a germline or somatic BRCA alteration.

54.8%

Confirmed PSA response rate

Median rPFS was **9.0** months per blinded IRR assessment.

Study met its primary endpoint!

Only Foundation Medicine offers an FDA-approved portfolio with both blood- and tissue-based comprehensive genomic profiling tests.

Fast results in less than two weeks[4]

FoundationOne Liquid CDx is FDA-approved as a companion diagnostic for RUBRACA® (rucaparib).

Although FoundationOne CDx is not an FDA-approved companion diagnostic for RUBRACA® at this time, this test does analyze *BRCA1* & *BRCA2*.

FoundationOne®CDx and FoundationOne®Liquid CDx are qualitative next-generation sequencing based *in vitro* diagnostic tests for advanced cancer patients with solid tumors and are for prescription use only. FoundationOne CDx utilizes FFPE tissue and analyzes 324 genes as well as genomic signatures. FoundationOne Liquid CDx analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes. The tests are companion diagnostics to identify patients who may benefit from treatment with specific therapies in accordance with the 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 tests does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy for testing with FoundationOne CDx when archival tissue is not available which may pose a risk. Patients who are tested with FoundationOne Liquid CDx and are negative for companion diagnostic mutations should be reflexed to tumor tissue testingand mutation status confirmed using an FDA-approved tumor tissue test, if feasible.

For the complete label, including companion diagnostic indications and important risk information, please visit *www.F1CDxLabel.com* and *www.F1LCDxLabel.com.*

References

1. Abida W, Patnaik A, Campbell D, et al. Rucaparib in Men With Metastatic Castration-Resistant Prostate Cancer Harboring a BRCA1 or BRCA2 Gene Alteration J Clin Oncol. August 14, 2020. DOI: 10.1200/JCO.20.01035
2. BRCA1: 2%; BRCA2: 10%
3. J Chung et al. Prospective Comprehensive Genomic Profiling of Primary and Metastatic Prostate Tumors JCO Precision Oncology. May 10, 2019. DOI: 10.1200/PO.18.00283
4. Typical results, from receipt of specimen at Foundation Medicine.

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