Unlocking New Treatment Options for Patients with Metastatic Prostate Cancer

FOUNDATION MEDICINE®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend Molecular Testing in Metastatic Prostate Cancer[1]

1 **Homologous recombination (HRD) pathway genes:** *BRCA1, BRCA2, ATM, PALB2, FANCA, RAD51D, CHEK2* and *CDK12* for genetic counseling, early use of platinum chemotherapy, olaparib, and/or eligibility for clinical trials (e.g., PARP inhibitors).

2 **Microsatellite instability (MSI) or mismatch repair deficiency (dMMR):** If MSI is used, testing using an NGS assay validated for prostate cancer is preferred. MSI or dMMR indicate eligibility for pembrolizumab in later lines of treatment for CRPC (castrate-resistant prostate cancer).†

Our portfolio of tests analyzes all guideline recommended genes and biomarkers for relevant alterations in patients with prostate cancer including: *BRCA1, BRCA2, ATM, PALB2, FANCA, RAD51D, CHEK2*, *CDK12* and MSI*.

Advancing Therapy Options for Metastatic Prostate Cancer Patients

BIOMARKER	FDA-APPROVED THERAPY	FOUNDATION MEDICINE COMPANION DIAGNOSTIC
Homologous Recombination Repair (HRR) gene (*BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D and RAD54L*) alterations	**Lynparza® (olaparib)**	**FoundationOne®CDx**
BRCA1, BRCA2	**Rubraca® (rucaparib)**	**FoundationOne®Liquid CDx**

As of June 2020
Lynparza® is a registered trademark of the AstraZeneca group of companies.
Rubraca® is a registered trademark of Clovis Oncology

The Value of Comprehensive Genomic Profiling with Foundation Medicine:

FoundationOne Liquid CDx is ***the only FDA-approved comprehensive genomic profiling test*** that can identify prostate cancer patients who are likely to respond to Rubraca® (rucaparib) from a simple blood draw.

By testing for all mutations, regardless of germline or somatic, our portfolio of tests can ***identify more than twice as many men who may benefit from PARP inhibitor therapy*** than conventional germline-only testing.

J Chung et al.
Prospective Comprehensive Genomic Profiling....[2]

A blood-based comprehensive genomic profiling test is an important option to consider for mCRPC patients due to tissue sample issues, as demonstrated in the TRITON2 trial for rucaparib where ***liquid biopsy identified an additional 22.5% of patients with a BRCA1/2 alteration for whom tissue was sample unavailable***[3], and in the PROfound trial for olaparib where ***31% of tissue samples were unable to be successfully sequenced*** for comprehensive genomic profiling testing.[4]

Due to genomic variance in metastatic sites, ***liquid biopsies may have advantages over individual metastatic site biopsies*** in their ability to capture the entire range of therapeutic opportunities for prostate cancer patients.[5]

* FoundationOne Liquid only reports MSI when determined to be high
† MSI/dMMR testing should be considered in patients with metastatic castration-naïve prostate cancer and is recommended in patients with metastatic CRPC.

FDA-approved portfolio of tests to help identify more treatment options:

FOUNDATIONONE®CDx

TISSUE BIOPSY

FoundationOne CDx is FDA-approved and covered by Medicare for qualifying patients[6].

- Analyzes 324 genes
- Reports TMB and MSI

FOUNDATIONONE®LIQUID CDx

LIQUID BIOPSY

FoundationOne Liquid CDx is FDA-approved and covered by Medicare for qualifying patients[6].

- Analyzes 324 genes◊
- bTMB, MSI-High, and tumor fraction◊

◊ FoundationOne Liquid CDx is FDA-approved to report substitutions and indels in 311 genes, including rearrangements and copy number losses only in *BRCA1/2*. Comprehensive results across all 324 genes, including bTMB, MSI-H status, and tumor fraction are reported in the professional services section of the report.

TO LEARN MORE:

Visit *www.foundationmedicine.com*

TO SIGN UP OR ORDER A TEST:

Visit *www.foundationmedicine.com/signup*

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 testing and mutation status confirmed using an FDA-approved tumor tissue test, if available. For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com and www.F1LCDxLabel.com.

References:

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2020 © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed May 27, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
2. J Chung et al. Prospective Comprehensive Genomic Profiling of Primary and Metastatic Prostate Tumors, JCO Precision Oncology, May 2019.
3. Abida, Wassim et al. Genomic characteristics associated with clinical activity of rucaparib in patients with BRCA1- or BRCA2-mutated metastatic castration-resistant prostate cnacer (mCRPC). Presented at ASCO GU 2020; February 13-15 2020; San Francisco, CA; Abstract 178.
4. Johann de Bono, M.B., et al (2020). Olaparib for Metastatic Castration-Resistant Prostate Cancer. New England Journal of Medicine. doi: 10.1056/nejmoa1911440
5. Necchi, Andrea et al. Comprehensive genomic profiling (CGP) in post-systemic treatment (Post) metastatic sites (MET) and pretreatment (Pre) primary tumors (PT) of metastatic prostate cancer (mPC). Journal of Clinical Oncology 38, no. 6_suppl (February 20, 2020) 175-175. DOI: 10.1200/JCO.2020.38.6_suppl.175
6. The Centers for Medicare & Medicaid Services (CMS) Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) see Appendix B.

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