Unlocking New Treatment Options for Patients with Metastatic Prostate Cancer

FOUNDATION MEDICINE®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend Molecular Testing in 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 (category 2B), 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

FDA-Approved Therapies, including the **bolded therapies** for which FoundationOne®CDx is the companion diagnostic

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

As of May 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:

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]

An IUO version of FoundationOne CDx used to screen patients in the PROfound trial found a ***17.1% frequency of BRCA1/2 or ATM***, and a ***27.9% frequency of HRR*** mutations.

Johann de Bono, M.B., et al.
Olaparib for Metastatic Castration-Resistant Prostate Cancer...[3]

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.[4]

* Only currently tested on FoundationOne CDx
† FoundationOne Liquid only reports MSI when determined to be high

A portfolio of tests to help identify more treatment options:

FOUNDATIONONE®CDx

TISSUE BIOPSY

FoundationOne CDx is FDA-approved with Medicare coverage for qualifying Medicare patients[5].

- Analyzes 324 genes
- Reports TMB and MSI

FOUNDATIONONE®LIQUID

LIQUID BIOPSY

FoundationOne Liquid is a laboratory developed test that delivers high-quality answers from a simple blood draw.

- Analyzes 70 genes
- Reports MSI-H status

TO LEARN MORE:

Visit *www.foundationmedicine.com*

TO SIGN UP OR ORDER A TEST:

Visit *www.foundationmedicine.com/signup*

FoundationOne CDx is the only FDA-approved *in vitro* diagnostic test by Foundation Medicine. FoundationOne Liquid was developed and its performance characteristics determined by Foundation Medicine. It has not been cleared or approved by the U.S. Food and Drug Administration. For more information on our laboratory developed tests (LDTs) please see their respective Technical Specifications at http://www.foundationmedicine.com.

FoundationOne®CDx is a next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific 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. Some patients may require a biopsy. For the complete label, including companion diagnostic indications and important risk information, please visit http://www.F1CDxLabel.com

References:

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.1.2019 © National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Accessed March 28, 2019. 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. Johann de Bono, M.B., et al (2020). Olaparib for Metastatic Castration-Resistant Prostate Cancer. New England Journal of Medicine. doi: 10.1056/nejmoa1911440
4. 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
5. Medicare and Medicare Advantage members have coverage of FoundationOne CDx in accordance with the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) criteria.

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