Unlocking New Treatment Options for Patients with Metastatic Prostate Cancer

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)
Recommend Molecular Testing in Prostate Cancer

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).

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†.

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).

Advancing Therapy Options for Metastatic Prostate Cancer Patients

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

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

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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.

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.

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

J Chung et al. Prospective Comprehensive Genomic Profiling...?
Johann de Bono, M.B., et al. Olaparib for Metastatic Castration-Resistant Prostate Cancer...?
### References:

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V1.2019 © 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.
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) 175S-175S. 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.