Unlocking new treatment options for Patients with Metastatic Breast Cancer

FOUNDATION MEDICINE®

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

1 | Therapeutic options are available for amplified and/or mutated ***ERBB2*** **(HER2)**

2 | Testing for germline ***BRCA1*** and ***BRCA2*** mutations should be considered in patients with HER2- metastatic breast cancer under consideration for chemotherapy

3 | Assess for ***PIK3CA*** mutation with tumor or liquid biopsy if patient has HR+/HER2- metastatic breast cancer

4 | For patients with metastatic triple-negative breast cancer (TNBC) assess PD-L1 biomarker status

Our portfolio of tests analyzes guideline recommended genes for relevant alterations in patients with breast cancer including *ERBB2* (HER2), *BRCA1/2**, and *PIK3CA* and offer a supplemental IHC-test for PD-L1.

Value of Comprehensive Genomic Profiling with Foundation Medicine:

Our tests detect additional alterations in genes known to be relevant in breast cancer, **such as *NTRK, ESR1, AKT1,*** as well as alterations in genes involved in the cell cycle pathway and the PI3K-AKT-mTOR and *HER2/FGFR* pathways.

Conveniently order supplemental PD-L1 testing that is the companion diagnostic for atezolizumab with your comprehensive tissue-based test all from one partner.

Breast cancer patients from all sub-types who have TMB ≥9 may benefit from cancer immunotherapy independent of their PD-L1 status or prior therapies.[2]

Alva AS, Mangat PK., Garrett-Mayer R, et al.,
Incidence of high tumor mutational burden...

Advancing Therapy Options in Breast Cancer

FDA-Approved therapies[3], including the **bolded therapies** for which FoundationOne CDx is the companion diagnostic

BIOMARKER	FDA-APPROVED THERAPY
ERBB2 **(HER2)** amplification	**Herceptin® (trastuzumab)** **Perjeta® (pertuzumab)** **Kadcyla® (ado-trastuzumab-emtansine)**
PIK3CA alterations	**Piqray® (alpelisib)**
HER2- and *BRCA1/2+*	Lynparza® (olaparib) Talzenna® (talazoparib)
MSI-H	Keytruda® (pembrolizumab)
NTRK fusions	Vitrakvi® (larotrectinib) Rozlytrek® (entrectonib)
PD-L1 expression[4]	Tecentriq® (atezolizumab) in combination with Abraxane®
TMB ≥ 10 mutations per megabase	**Keytruda® (pembrolizumab)**

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

Growing Therapy Options in Breast Cancer

Genomic alterations and relevance for clinical trials with novel therapies[5]

MOLECULAR ALTERATION	SUBTYPE CONSIDERATION	→ DRUG CLASS
ERBB2 mutation	2%–4% breast cancer	HER2 Tyrosine kinase inhibitors (TKI)
AKT1 mutation	2%–5% breast cancer	*AKT* inhibitor, mTor inhibitor
ESR1 mutation	30%–40% *ER+/HER2-* after aromatase inhibitors (AI)	Selective estrogen receptor degrader
TMB ≥9	8–12% breast cancers[2]	Immune checkpoint inhibitor

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

FOUNDATIONONE®CDx

TISSUE BIOPSY

FoundationOne CDx is FDA-approved and includes Medicare coverage for qualifying patients[6].

- Analyzes 324 genes
- Reports TMB and MSI

FOUNDATIONONE®LIQUID CDx

LIQUID BIOPSY

FoundationOne®Liquid CDx is FDA-approved and includes Medicare coverage 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 feasible.

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 Breast Cancer V.5.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed July 29, 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. Alva AS, Mangat PK, Garrett-Mayer E, et al: Pembrolizumab (P) in patients (pts) with metastatic breast cancer (MBC) with high tumor mutational burden (HTMB): Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study. J Clin Oncol 37, 2019 (suppl; abstr 1014)
3. Herceptin®, Perjeta®, and Kadcyla® are registered trademarks of Genentech, Inc. Lynparza® is a registered trademark of the AstraZeneca group of companies. Talzenna® is a registered trademark of Pfizer Inc. Brandname® is a registered trademark of Novartis. Keytruda® is a registered trademark of Merck Sharp & Dohme Corp. a subsidiary of Merck & Co., Inc. Vitrakvi® is a registered trademark of Bayer. Piqray® is a registered trademark of Novartis.
4. VENTANA PD-L1 (SP142) assay is the companion diagnostic for atezolizumab and can be ordered a supplemental test to tissue-based testing with Foundation Medicine.
5. Kratz, J et al. Incorporating Genomics Into the Care of Patients With Advanced Breast Cancer American Society of Clinical Oncology Educational Book 2018 :38, 56-64
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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