Uncovering Treatment Options for Patients with Non-Small Cell Lung Cancer (NSCLC)

FOUNDATION MEDICINE®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommend Molecular Testing for Appropriate Patients with Metastatic NSCLC, if Clinically Feasible[1*†]

FOR ADENOCARCINOMA, LARGE CELL, AND NSCLC NOT OTHERWISE SPECIFIED (NOS)

1 Recommend biomarker testing for *EGFR, ALK, ROS1, BRAF, MET* exon 14 skipping, *RET, NTRK*, and PD-L1*, and emerging biomarkers *MET* amplification, *ERBB2* (HER2) and TMB.

2 Strongly advise broader molecular profiling with the goal of identifying rare driver mutations for which effective drugs may already be available, or to appropriately counsel patients regarding the availability of clinical trials.[1]

3 The use of plasma cell-free/circulating tumor DNA (plasma testing) can be considered in specific clinical circumstances such as a patient unfit for invasive tissue sampling or if there is insufficient material for molecular analysis following pathologic confirmation of a NSCLC diagnosis.[1]

* The NCCN Guidelines® for NSCLC provide recommendations for individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays.
† National Comprehensive Cancer Network® (NCCN®).

Our portfolio of tests analyzes genes and biomarkers for relevant alterations in patients with NSCLC, including *EGFR, ALK, ROS1, BRAF, MET, RET, NTRK, ERBB2,* TMB‡ and PD-L1.§

Expanding FDA-Approved Therapy Options for Metastatic NSCLC patients

FoundationOne®CDx is a companion diagnostic
FoundationOne®Liquid CDx is a companion diagnostic

EGFR
Gilotrif® (afatinib)
Iressa® (gefitinib)
Tagrisso® (osimertinib)
Tarceva® (erlotinib)
Vizimpro® (dacomitinib)

ALK
Alecensa® (alectinib)
Alunbrig® (brigatinib)
Xalkori® (crizotinib)
Zykadia® (ceritinib)

ROS1
Rozlytrek® (entrectinib)
Xalkori® (crizotinib)
Zykadia® (ceritinib)

BRAF V600E
Tafinlar® (dabrafenib)
in combination with
Mekinist® (trametinib)
Zelboraf® (vemurafenib)

MET
Trabecta® (capmatinib)

RET
Retevmo™ (selpercatinib)

NTRK
Rozlytrek® (entrectinib)
Vitrakvi® (larotrectinib)

PD-L1
Keytruda® (pembrolizumab)
Tecentriq® (atezolizumab)
in combination with chemotherapy

TMB
Keytruda® (pembrolizumab)

The Value of Comprehensive Genomic Profiling with Foundation Medicine

Single gene testing or limited panels have been shown to *miss up to 35% of ALK fusions[2] and 21% of EGFR mutations* (41% of these missed *EGFR* mutations are common alterations targetable by an FDA-approved therapy in the applicable patient's tumor type)[3].

Foundation Medicine is the *only company that has demonstrated the ability for a comprehensive blood-based test* to identify patients with ALK fusions in a global prospective trial for metastatic NSCLC at similar frequencies historically published with tissue testing[4], as shown with our previous laboratory developed test FoundationOne®Liquid^Δ.

A study in NSCLC found that *44% of patients didn't get results from molecular testing* because tissue was insufficient[5]. In such cases, a portfolio that includes liquid-based comprehensive genomic profiling provides the option to automatically reflex to liquid.

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 Microsatellite Instability (MSI)

Total: ***10 SLIDES or 1 FFPE BLOCK***

Typical turnaround time is <2 weeks from receipt of specimen

IHC Testing for PD-L1

Optional add-on with 4 additional slides

Typical turnaround is 5 days from receipt of specimen

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◊

Total: ***TWO 8.5mL TUBES of PERIPHERAL WHOLE BLOOD***

Typical turnaround time is <2weeks from receipt of specimen

TO LEARN MORE:

Visit *www.foundationmedicine.com*

TO SIGN UP OR ORDER A TEST:

Visit *www.foundationmedicine.com/signup*

‡ FoundationOne Liquid CDx reports on bTMB.

§ PD-L1 by immunohistochemistry (IHC) can be ordered as a supplemental test and may inform eligibility for several immunotherapies across different cancer types.

Δ FoundationOne®Liquid is a previous version and different from FoundationOne®Liquid CDx. For concordance results between these two tests, please see our label at www.foundationmedicine.com/F1LCDx.

◊ 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.

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 NSCLC V.6.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed June 30, 2020. To view the most recent and complete version of the guideline, go online to *NCCN.org*.
2. Ali SM, et al. Comprehensive genomic profiling identifies a subset of crizotinib-responsive ALK-rearranged non-small cell lung cancer not detected by FISH. The Oncologist. 2016 Jun;21(6):762-770.
3. Suh J, et al. Hybrid Capture-Based Comprehensive Genomic Profiling Identifies Lung Cancer Patients with Well-Characterized Sensitizing Epidermal Growth Factor Receptor Point Mutations That Were Not Detected by Standard of Care Testing. The Oncologist. 2018;23:776-781.
4. LBA81_PR 'Phase II/III blood first assay screening trial (BFAST) in patients (pts) with treatment-naïve NSCLC: initial results from ALK+ cohort' will be presented by Shirish Gadgeel during the proffered paper session on Monday, 30 September 2019, 08:30-10:00 CEST in Madrid Auditorium (Hall 2). Annals of Oncology, Volume 30, Supplement 5, October 2019.
5. Frampton GM, et al. Development and validation of a clinical cancer genomic profiling test based on massively parallel DNA sequencing. Nat Biotech 2013;11:1023-1033.
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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