MI PROFILE™

Final Report

CARIS LIFE SCIENCES

Patient

Name: Patient, Test
Date of Birth: XX/Mon/19XX
Sex: Female
Case Number: TN19-XXXXXX
Diagnosis: Sarcomatoid carcinoma

Specimen Information

Primary Tumor Site: Anterior wall of bladder
Specimen Site: Bladder, NOS
Specimen ID: ABC-1234-XYZ
Specimen Collected: XX-Mon-2019
Completion of Testing: XX-Mon-2019

Ordered By

Ordering Physician, MD
Cancer Center
123 Main Street
Springfield, XY 12345, USA
1 (123) 456-7890

High Impact Results

BIOMARKER	METHOD	RESULT	THERAPY ASSOCIATION		BIOMARKER LEVEL*
PD-L1	**22c3 IHC-CPS**	**Positive, CPS: 60**	**BENEFIT**	**pembrolizumab**	**Level 1**

* Biomarker reporting classification: Level 1 - highest level of clinical evidence and/or biomarker association included on the drug label; Level 2 - strong evidence of clinical significance and is endorsed by standard clinical guidelines; Level 3 - potential clinical significance (3A - evidence exists in patient's tumor type, 3B - evidence exists in another tumor type).

Important Note

Please note that PDL1 CPS score is 60 (>=10). CPS is calculated as the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total viable tumor cells, multiplied by 100. Threshold for positive staining is a CPS >=10. This PD-L1 score is sufficient for use of pembrolizumab in the front-line metastatic setting. Use of pembrolizumab is FDA approved for the treatment of locally advanced or metastatic bladder cancer who are not eligible for cisplatin-containing chemotherapy with a PD-L1 CPS>=10, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

Additional Results

CANCER TYPE RELEVANT BIOMARKERS

Biomarker	Method	Result
MSI	NGS	Stable
Mismatch Repair Status		Proficient
NTRK1	RNA-Seq	Fusion Not Detected
NTRK2	RNA-Seq	Fusion Not Detected
NTRK3	RNA-Seq	Fusion Not Detected
Tumor Mutational Burden		High | 19 Mutations/Mb
ATM	NGS	Mutation Not Detected
ERBB2 (Her2/Neu)	NGS	Mutation Not Detected
ERCC2	NGS	Mutation Not Detected
FANCC	NGS	Mutation Not Detected
FGFR1	RNA-Seq	Fusion Not Detected

CANCER TYPE RELEVANT BIOMARKERS (cont)

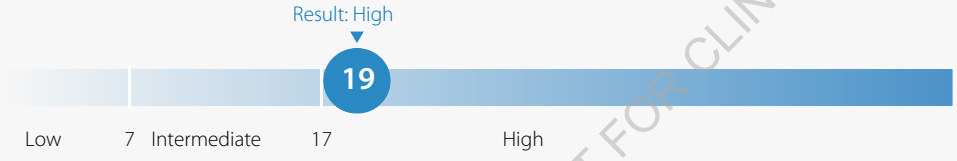
Biomarker	Method	Result
FGFR2	RNA-Seq	Fusion Not Detected
FGFR3	NGS	Mutation Not Detected
	RNA-Seq	Fusion Not Detected
RB1	NGS	Mutation Not Detected
TSC1	NGS	Mutation Not Detected

OTHER FINDINGS (see page 2 for additional results)

Biomarker	Method	Result
ARID1A	NGS	Mutated, Pathogenic
		Exon 3 | p.Q479*
ERBB3	NGS	Mutated, Presumed Pathogenic
		Exon 3 | p.M91I

Biomarker Results

This summary includes biomarkers most commonly associated with cancer. Complete details of all biomarkers tested can be found in the Appendix.

GENOMIC SIGNATURES		
Biomarker	**Method**	**Result**
Microsatellite Instability (MSI)	NGS	Stable
Tumor Mutational Burden (TMB)	NGS	

GENES TESTED WITH MUTATIONS/ALTERATIONS						
Gene	**Method**	**Variant Interpretation**	**Protein Alteration**	**Exon**	**DNA Alteration**	**Variant Frequency %**
ARID1A	NGS	Mutated, Pathogenic	p.Q479*	3	c.1435C>T	14
BRCA2	NGS	Mutated, Variant of Unknown Significance	p.S1667L	11	c.5000C>T	15
ERBB3	NGS	Mutated, Presumed Pathogenic	p.M91I	3	c.273G>A	38
TP53	NGS	Mutated, Pathogenic	p.Q331*	9	c.991C>T	38

Transcript ID and Variants of Unknown Significance can be found in the Appendix.

Other Findings

IMMUNOHISTOCHEMISTRY (IHC)			
Biomarker	**Result**	**Biomarker**	**Result**
MLH1	Positive | 2+, 90%	PD-L1 (22c3)	Positive, CPS: 60
MSH2	Positive | 2+, 100%	PMS2	Positive | 1+, 100%
MSH6	Positive | 2+, 95%		

GENES TESTED WITHOUT POINT MUTATIONS OR INDELS BY NGS											
ATM	BRAF	BRCA1	CCND1	CDKN2A	EGFR	ERBB2 (Her2/ Neu)	ERCC2	FANCC	FGFR3	HRAS	IDH1
KIT	KRAS	MET	MTOR	NRAS	NTRK1	NTRK2	NTRK3	PDGFRA	PIK3CA	RB1	RET
TSC1											

Additional results continued on the next page. >

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Clinical Trials Connector™

For a complete list of open, enrolling clinical trials visit MI Portal to access the **Clinical Trials Connector**. This personalized, real-time web-based service provides additional clinical trial information and enhanced searching capabilities, including, but not limited to:

- Location: filter by geographic area
- Biomarker(s): identify specific biomarkers associated with open clinical trials to choose from
- Drug(s): search for specific therapies
- Trial Sponsor: locate trials based on the organization supporting the trial(s)

Visit www.CarisMolecularIntelligence.com to view all matched trials. Therapeutic agents listed below may or may not be currently FDA approved for the tumor type tested.

TARGETED THERAPY CLINICAL TRIALS (211)			
Drug Class	**Biomarker**	**Method**	**Investigational Agent(s)**
Akt inhibitors (4)	ARID1A	NGS	ARQ092, AZD5363
Cell cycle inhibitors (3)	TP53	NGS	LY2606368
Immunomodulatory agents (196)	PD-L1	IHC	MEDI4736, MK-3475, MPDL3280A, MSB0010718C, atezolizumab, avelumab, durvalumab, nivolumab, pembrolizumab
	TMB	NGS	
Pan-HER inhibitors (8)	ERBB3	NGS	afatinib, lapatinib, neratinib, pyrotinib

( ) = represents the total number of clinical trials identified by the Clinical Trials Connector for the provided drug class or table.

Please refer to the "Notes of Significance" section that may contain additional information regarding therapy associations.

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CLIA 03D1019490 • CAP 7195577 • ISO 15189:2012 • Zoran Gatalica, MD, DSc, Medical Director •

To view the rest of the report, contact a Caris Molecular Intelligence® representative today.

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