[Oncofocus] Patient Test Report

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ONC17			
Surname		**Requesting Clinician**	
Forename			
DOB		**Date requested**	
Gender	Male		
Histology #		**Tumour %**	40%
Primary site	Bone	**Tumour %**	-
Tumour subtype	Osteosarcoma	**(macrodissected)**	
Tissue Type	C6 Vertebra		

Comment:

The DNA and RNA extracted from this sample were of optimal quality. The Oncofocus assay on which the sample was run met all assay specific quality metrics.

237 genes were targeted using 2530 unique amplicons covering oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors. Actionable genetic variants detected by Oncofocus are linked to 582 anti-cancer targeted therapies.

The following actionable variants were detected:

Variant Summary

Sample Cancer Type: Osteosarcoma

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

Gene Variant	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials
CDKN2A deletion	✖	✖	✖	✖	● (2)

EMA: European Medicine Agency, **US-FDA:** United States-Food and Drug Administration, **ESMO:** European Society for Medical Oncology, **US-NCCN:** United States-National Comprehensive Cancer Network. Numbers in parentheses indicate the number of relevant therapies with evidence. Hotspot variants with >10% alternate allele reads, and in >10 unique reads are classified as 'detected' with an assay sensitivity and positive predictive value(PPV) of 92%. Copy number variants; amplifications of CN> 6 with the 5% confidence value of ≥4 after normalization and deletions with 95% CI ≤1 are classified as present when the tumour% >50% with a sensitivity of 80% and PPV 100%. Gene Fusions are reported when occurring in >20 counts and meeting the thresholds of assay specific internal RNA quality control with a sensitivity of 92% and PPV of 99%. Supplementary technical information is available upon request.

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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Relevant Therapy Summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

CDKN2A deletion

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
ilorasertib	✖	✖	✖	✖	● (II)
palbociclib	✖	✖	✖	✖	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.

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Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-12-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

CDKN2A deletion

NCT02478320
A Proof-of-Concept Study for Ilorasertib (ABT-348) Activity in Patients With CDKN2A-Deficient Advanced Solid Cancers: a Phase II Basket Trial

Cancer type: Unspecified Solid Tumor

Variant class: CDKN2A deletion

Other identifiers: 2014-0920, NCI-2015-01251, TrialTroveID-260223

Population segments: Line of therapy N/A, Stage III, Stage IV

Phase: II

Therapy: ilorasertib

Location: United States

US State: TX

US Contact: Dr. David S. Hong [713-563-1930]

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: CDKN2A deletion

Other identifiers: Pro00014171, TAPUR, TrialTroveID-273941

Population segments: (N/A), Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: palbociclib

Location: United States

US States: IL, MI, NC, PA, SD

US Contact: Pam Mangat [pam.mangat@asco.org]

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CDKN2A deletion (continued)

NCT01037790
Phase II Trial of the Cyclin-Dependent Kinase Inhibitor PD 0332991 in Patients With Cancer

Cancer type: Unspecified Solid Tumor

Variant class: G1/S cell cycle pathway

Other identifiers: NCI-2009-01467, Study 1006, TrialTroveID-120590, UPCC 03909, UPCC03909

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Metastatic, Progesterone receptor positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: II

Therapy: palbociclib

Location: United States

US State: PA

US Contact: Peter O'Dwyer [855-216-0098; PennCancerTrials@emergingmed.com]

NCT02540876
A Pilot Study for Ilorasertib (ABT-348) in Patients With CDKN2A-deficient Advanced Solid Cancers: A Series of Individual Patient Cross-Over Studies With Growth Trajectory Assessment

Cancer type: Unspecified Solid Tumor

Variant class: CDKN2A deletion

Other identifiers: AbbVie IIS-10750, IRB15-0083, NCI-2015-01328, P30CA014599, TrialTroveID-264142

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: ilorasertib

Location: United States

US State: IL

US Contact: Linda L. Janisch [773-702-1612; ljanisch@medicine.bsd.uchicago.edu]

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Appendix: Evidence Summary by Variant Class

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

CDKN2A deletion

Variant Class	Evidence Items
G1/S cell cycle pathway	1
↳ CDKN2A negative	0
↳ CDKN2A deletion	3

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