[Oncofocus] Patient Test Report

Oncologica UK Ltd
Suite 15-16, The Science Village
Chesterford Research Park
Cambridge, CB10 1XL, UK
Tel: +44(0)1223 785327
Email: info@oncologica.com

Histology #		**Tumour %**	40%
Primary site	Gastric	**Tumour % (macrodissected)**	
Tumour subtype	Poorly Differentiated Adenocarcinoma		
Tissue type	Oesophageal gastric junction		

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.

221 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 485 anti-cancer targeted therapies.

A variant of unknown significance was identified in the ATM gene: c.6096A>T p.(Arg2032Ser)
This is missense mutation and therefore may have a deleterious effect on ATM function. Although there is no published functional data on this particular variant, if it does cause ATM aberration, then the therapies identified in this report would be indicated.

Variant Summary

Sample Cancer Type: Gastric Cancer

● 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
MDM2 amplification	✖	✖	✖	✖	● (1)
ATM c.6096A>T p.(Arg2032Ser)	✖	✖	✖	✖	● (1)

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 of 97%. Copy number variants; amplifications of a >5% confidence value of ≥4 after normalization and deletions of ≤1 are classified as present when the tumour% >50%. Gene Fusions are reported when occurring in >20 counts and meeting the thresholds of assay specific internal RNA quality control. With a sensitivity of 99% 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

MDM2 amplification

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
AMG-232	✖	✖	✖	✖	● (I)

ATM mutation

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
olaparib	✖	✖	✖	✖	● (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 2016-09-01. 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'.

MDM2 amplification

NCT01723020
A Phase I First-in-Human Study Evaluating the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of AMG 232 in Adult Subjects With Advanced Solid Tumors or Multiple Myeloma

Cancer type: Unspecified Solid Tumor

Variant class: MDM2 amplification

Other identifiers: 14-118, 15-306, 20120106, CSET 2094, EudraCT Number: 2012-002908-41, NCI-2014-02184, NL41417.078.12, TrialTroveID-177265

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

Other inclusion criteria: TP53 wild type

Phase: I

Therapy: AMG-232

Countries: France, Netherlands, United States

US States: CA, CT, MA, NJ, NY, SC

US Contact: Amgen Call Center [866-572-6436]

ATM mutation

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: ATM mutation

Other identifiers: Pro00014171, TAPUR, TrialTroveID-273941

Population segments: (N/A), Aggressive, Diffuse large B-cell lymphoma (DLBCL), Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: olaparib

Country: United States

US States: MI, NC

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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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.

MDM2 amplification

Variant Class	Evidence Items
MDM2 amplification	1

ATM mutation

Variant Class	Evidence Items
ATM mutation	1

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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