[Oncofocus] Patient Test Report

Oncologica UK Ltd
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ONC16-0224

Surname		**Requesting clinician**	
Forename			
DOB		**Date requested**	
Gender			
Histology #		**Tumour %**	70
Primary site	Ovary	**Tumour % (macrodissected)**	
Tumour subtype	Serous Adenocarcinoma		
Tissue type	Ovary		

Comment: This is a final report which replaces the interim report (dated 14/12/16) and reflects the results from additional testing.
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.

The following actionable variants were detected:

Notably the TP53 and BRCA1 aberrations was detected are at a high allele frequency raising the possibility that these are germline mutations. However, the Oncofocus test is unable to distinguish somatic from germline mutations.

Variant Summary

Sample Cancer Type: Ovarian 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
BRCA1 p.(A1714fs) c.5139_5140insAT	● (1)	✖	✖	✖	● (5)
TP53 p.(R196Ter) c.586C>T	✖	✖	✖	✖	● (9)
MYC amplification	✖	✖	✖	✖	● (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

BRCA1 p.(A1714fs) c.5139_5140insAT

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
olaparib	●	✖	✖	✖	● (IV)
niraparib	✖	✖	✖	✖	● (III)
bevacizumab, bevacizumab + niraparib, niraparib	✖	✖	✖	✖	● (I/II)
olaparib + chemotherapy	✖	✖	✖	✖	● (I/II)
talazoparib + chemotherapy	✖	✖	✖	✖	● (I)

TP53 p.(R196Ter) c.586C>T

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
MK-1775 + chemotherapy	✖	✖	✖	✖	● (II)
MK-1775 + olaparib	✖	✖	✖	✖	● (II)
APR-246 + chemotherapy	✖	✖	✖	✖	● (I/II)
ganetespib + chemotherapy	✖	✖	✖	✖	● (I/II)
chemotherapy + p53MVA	✖	✖	✖	✖	● (I)
COTI-2	✖	✖	✖	✖	● (I)
ixazomib + vorinostat	✖	✖	✖	✖	● (I)
MK-1775	✖	✖	✖	✖	● (I)
SGT-53, SGT-53 + chemotherapy	✖	✖	✖	✖	● (I)

* 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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Relevant Therapy Summary (continued)

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

MYC amplification

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
INCB-54329	✖	✖	✖	✖	● (I/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 EMA Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

EMA information is current as of 2016-10-03. For the most up-to-date information, search www.ema.europa.eu/ema.

BRCA1 p.(A1714fs) c.5139_5140insAT

● olaparib

Cancer type: Ovarian Cancer **Label as of:** 2016-04-13 **Variant class:** BRCA mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003726/WC500180151.pdf

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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'.

BRCA1 p.(A1714fs) c.5139_5140insAT

NCT02476968
An Open Label, Single Arm, Multicentre Study to Assess the Clinical Effectiveness and Safety of Lynparza (Olaparib) Capsules Maintenance Monotherapy in Platinum Sensitive Relapsed Somatic or Germline BRCA Mutated Ovarian Cancer Patients Who Are in Complete or Partial Response Following Platinum Based Chemotherapy (ORZORA).

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

Other identifiers: D0816C00012, EudraCT Number: 2015-000734-30, IRAS ID: 177196, ORZORA, REec-2015-1634, TrialTroveID-260119

Population segments: (N/A), Maintenance/Consolidation, Second line or greater/ Refractory/Relapsed

Phase: IV

Therapy: olaparib

Countries: Bulgaria, Canada, Czech Republic, Hungary, Italy, Poland, Spain, United Kingdom

NCT02503436
C-PATROL - A Single Arm, Prospective Non-interventional Study (NIS) to Collect Clinical and Patient Reported Outcome Data in an Olaparib Treated BRCAm+ PSR Ovarian Cancer Population

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

Other identifiers: C-PATROL, D0816R00009, TrialTroveID-261874

Population segments: (N/A), Maintenance/Consolidation

Phase: IV

Therapy: olaparib

Country: Germany

NCT02655016
A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients With HRD-Positive Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

Other identifiers: ENGOT-ov 26, EudraCT Number: 2015-000952-11, NCI-2016-00574, PR-30-5017-C, PRIMA, TrialTroveID-252552

Population segments: Maintenance/Consolidation, Stage III, Stage IV

Phase: III

Therapy: niraparib

Country: United States

US States: CA, LA, MA, MD, NY, OH, OK, OR, PA, SD, WA

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

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.

BRCA1 p.(A1714fs) c.5139_5140insAT (continued)

NCT02684318
Phase Ib/II Study to Evaluate the Efficacy and Tolerability of PM01183 in Combination With Olaparib in Patients With Advanced Solid Tumors

Cancer type: Ovarian Cancer

Variant class: BRCA1 mutation

Other identifiers: EudraCT Number: 2015-001141-80, POLA, POLA/ACOG1401, TrialTroveID-263173

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage I, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: olaparib + chemotherapy

Country: Spain

NCT02354131
AVANOVA1 - Phase I of Bevacizumab-Niraparib Combination. AVANOVA2 -A 3-arm, Phase II Randomized Study of Niraparib &/or Niraparib-bevacizumab Combination Against Bevacizumab Alone in HRD Platinum-sensitive Epithelial Ovarian Cancer.

Cancer type: Ovarian Cancer

Variant class: BRCA mutation

Other identifiers: AVANOVA, AVANOVA1, AVANOVA2, ENGOT-ov24 - AVANOVA: NSGO, ENGOT-OV24-NSGO/AVANOVA, EudraCT Number: 2014-004269-26, TrialTroveID-251559

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: I/II

Therapies: bevacizumab, bevacizumab + niraparib, niraparib

Country: Denmark

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: BRCA1 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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BRCA1 p.(A1714fs) c.5139_5140insAT (continued)

NCT02317874
A Phase I Study of BMN 673 in Combination with Carboplatin and Paclitaxel in Patients with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRCA1 mutation

Other identifiers: 051513, 9782, NCI 9782, NCI-2014-02474, TrialTroveID-248774

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

Phase: I

Therapy: talazoparib + chemotherapy

Country: United States

US States: NJ, WI

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

TP53 p.(R196Ter) c.586C>T

NCT02272790
A Multicentre Phase II Study of AZD1775 Plus Chemotherapy in Patients With Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Cancer type: Ovarian Cancer

Variant class: TP53 mutation

Other identifiers: 14-268, 14-547, 15401, 18114, AAAO8156, D6010C00004, EudraCT Number: 2015-000886-30, IRAS ID: 168445, TrialTroveID-219301

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: II

Therapy: MK-1775 + chemotherapy

Countries: Canada, United Kingdom, United States

US States: AZ, CA, FL, GA, MA, NY, OH, OK, OR, PA, TN, TX, WI

US Contact: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

NCT02098343
PiSARRO: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin Combination Chemotherapy With or Without APR-246

Cancer type: Ovarian Cancer

Variant class: TP53 mutation

Other identifiers: APR-246-02, APR-407, EudraCT Number: 2013-001472-38, EUTROC PiSARRO, IRAS 137274, PiSARRO, REec-2016-2092, TrialTroveID-128680

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: I/II

Therapy: APR-246 + chemotherapy

Countries: Belgium, Netherlands, Spain, United Kingdom

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.

TP53 p.(R196Ter) c.586C>T (continued)

NCT02012192
A Two-part, Multicentre, International Phase I and II Trial Assessing the Safety and Efficacy of the Hsp90 Inhibitor Ganetespib in Combination With Paclitaxel Weekly in Women With High-grade Serous, High-grade Endometrioid, or Undifferentiated, Platinum-resistant Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer Ganetespib in metastatic, p53 mutant, platinum-resistant ovarian cancer (GANNET53)

Cancer type: Ovarian Cancer

Variant class: TP53 mutation

Other identifiers: DRKS00005501, EudraCT Number: 2013-003868-31, GANNET53, TrialTroveID-199233

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

Phase: I/II

Therapy: ganetespib + chemotherapy

Countries: Austria, Belgium, France, Germany

NCT02275039
A Phase I Study of a p53MVA Vaccine in Combination With Gemcitabine in Ovarian Cancer

Cancer type: Ovarian Cancer

Variant class: TP53 mutation

Other identifiers: 13373, NCI-2014-02169, TrialTroveID-219643

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: I

Therapy: chemotherapy + p53MVA

Country: United States

US State: CA

US Contact: Mihaela C. Cristea [800-826-4673; becomingapatient@coh.org]

NCT02433626
A Phase 1b Study of Coti-2 for the Treatment of Advanced or Recurrent Gynecologic Malignancies

Cancer type: Ovarian Cancer

Variant class: TP53 mutation

Other identifiers: 2015-0035, COTI2-101, DRUG COTI2-101, NCI-2015-01738, TrialTroveID-198183

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

Phase: I

Therapy: COTI-2

Country: United States

US States: IL, TX

US Contact: Ashley ten Haaf [519-858-5157; atenhaaf@criticaloutcome.com]

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TP53 p.(R196Ter) c.586C>T (continued)

NCT02576444
A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD2014 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 1508016363, OLAPCO, TrialTroveID-266161

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

Phase: II

Therapy: MK-1775 + olaparib

Country: United States

US State: CT

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

NCT02042989
A Phase I Study of MLN9708 and Vorinostat to Target Autophagy in Patients With Advanced p53 Mutant Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 2013-0511, NCI-2014-01091, TrialTroveID-201319

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

Phase: I

Therapy: ixazomib + vorinostat

Country: United States

US State: TX

US Contact: Dr. Siqing Fu [713-563-1930]

NCT02610075
A Phase Ib Study to Determine the Maximum Tolerated Dose (MTD) of AZD1775 Monotherapy in Patients With Locally Advanced or Metastatic Solid Tumours.

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: D6015C00003, REFMAL 398, TrialTroveID- 268385

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

Phase: I

Therapy: MK-1775

Country: United States

US States: CO, TN

US Contact: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

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TP53 p.(R196Ter) c.586C>T (continued)

NCT02354547
A Phase I Study of SGT-53, a TfRscFv-Liposome-p53 Complex, in Children with Refractory or Recurrent Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 1405-1316, SGT53-01-2, TrialTroveID-251586

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: I

Therapies: SGT-53, SGT-53 + chemotherapy

Country: United States

US State: TX

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

MYC amplification

NCT02431260
A Phase I, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054329 in Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: MYC aberration

Other identifiers: 2015-0054, INCB 54329-101, NCI-2015-00936, TrialTroveID-252118, UMCC 2015.032, UW15024

Population segments: Aggressive, Classical, Diffuse large B-cell lymphoma (DLBCL), Hormone refractory, Indolent, Nodular lymphocyte-predominant, Other subtype, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I/II

Therapy: INCB-54329

Country: United States

US States: CA, CO, IL, IN, MI, MO, TN, TX, WA

US Contact: Incyte Corporation Call Center [855-463-3463]

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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.

BRCA1 p.(A1714fs) c.5139_5140insAT

Variant Class	Evidence Items
BRCA mutation	3
↳ BRCA1 mutation	5

TP53 p.(R196Ter) c.586C>T

Variant Class	Evidence Items
TP53 mutation	9

MYC amplification

Variant Class	Evidence Items
MYC aberration	1
↳ MYC amplification	0

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Appendix: Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency	Transcript	Variant Effect
BRCA1	p.(A1714fs)	c.5139_5140insAT	.	chr17:41215966	65.29%	NM_007300.3	frameshift Insertion
TP53	p.(R196Ter)	c.586C>T	.	chr17:7578263	49.77%	NM_000546.5	nonsense

Copy Number Variations

Gene	Locus	Copy Number
MYC	chr8:128748884	5.1

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Report Signed by		Report Checked by	
			
Clinical Scientist	☑		
Pathologist	☐	BMS	☑
BMS (Senior)	☐		

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The following paragraph on Liability is an extract from the Oncologica Tests' Terms and Conditions. The extract is to draw your attention to particular terms applicable to you but nothing set out here is intended to supersede or override our Terms and Conditions, which can be found on our website at www.oncologica.com under the title Oncologica Tests' Terms and Conditions. Please read these Oncologica Test Terms and Conditions carefully before you submit an order for the Oncologica Tests, as you will be bound by these Terms and Conditions, once a contract comes into existence as per paragraph 2 of the Oncologica Test's Terms and Conditions.

6. Liability

6.1 Oncologica operates in compliance with international ISO15189:2012 standards and is regulated by UKAS. The Oncologica Tests have not been cleared or approved by the United States Food and Drug Administration; however, such clearance or approval is not required.

6.2 The Patient agrees that the Oncologica Test Report is intended for clinical use and interpretation by a physician who is experienced and skilled in the use and interpretation of clinical test data. The Oncologica Test Report is based on the Sample submitted by the Patient. The Oncologica Test Report should not be considered or its contents applied to any other patient or any other sample. Oncologica does not update an Oncologica Test Report once it has been sent.

6.3 Information compiled in the Oncologica Test Report includes is from publicly available as well as proprietary sources. By updating the source database, Oncologica makes every effort to provide the most accurate and up-to-date information. However, Oncologica does not warrant or represent that the information in the Oncologica Test Report is accurate, timely or complete.

6.4 The Oncologica Test Report contains drug and clinical trial information. However, Oncologica does not warrant or represent that any drug or clinical trial identified by the Oncologica Test will guarantee a therapeutic response for a particular Patient. The drugs listed in an Oncologica Test Report are ranked on clinical evidence as to the predicted efficacy or appropriateness for the Patient. The Patient shall ensure that its physician shall evaluate and interpret the Oncologica Test Report, along with all other available clinical information about the Patient, to determine the best treatment decisions in their own independent medical judgment. Patient management decisions should not be based on a single test, nor solely on the information contained in the Oncologica Test Report.

6.5 Subject to paragraph 6.10, Oncologica shall have no liability for any use made of the information provided in the Oncologica Test Report, including but not limited to any report prepared by Oncologica summarising the results of the Oncologica Tests, any advice supplied by Oncologica, any decisions taken, or for any costs incurred by Patient and/or the Patient's physician and/or the Agent in consequence of such use, advice or decisions. The Oncologica Test and/or the Oncologica Test Report is not a substitute for the Patient's physician's professional judgment. The use of the information provided in the Oncologica Test Report is provided as a tool for the ordering physician's use in determining the appropriate treatment for the Patient. The decision as to what course of treatment and the appropriate use of the information provided by the Oncologica Test Report is solely that of the Patient's physician.

6.6 Oncologica does not warrant or represent or guarantee that the Oncologica Tests will identify an actionable genetic alteration that is linked to anti-cancer targeted therapies. Although the Oncologica Tests are comprehensive, in a proportion of Patients, the Oncologica Test result may not identify any actionable mutations for a patient's cancer. In the event that no actionable alteration in the Sample is identified by the Oncologica Test, then the Patient is still under full obligation to pay the Charges and no refund is available to the Patient and/or Agent.

6.7 The Oncologica Test identifies genomic actionable alterations found in the submitted Sample that are linked to anti-cancer targeted agents. Also note that this test only examines tumour, and not normal tissue from the patient, and therefore cannot distinguish between somatic and germline (i.e., heritable) alterations.

6.8 Subject to Clause 6.8, Oncologica shall not be liable to the Patient whether in contract, tort (including negligence and breach of statutory duty), or otherwise for any:

(a) Error or defect in the Oncologica Test Report as a result of any inaccurate or incomplete information supplied by the Patient;

(b) Loss of data or materials, including the Sample and/or the Report and including any loss arising as a result of the acts or omissions of a courier;

(c) Indirect or consequential loss arising whether or not advised of the possibility of the same.

6.9 Subject to the provisions of this Clause 6, Oncologica's total liability to the Patient in respect of all losses arising under or in connection with the Contract, whether in contract, tort (including negligence and breach of statutory duty), or otherwise, shall in no circumstances exceed the Charges paid for the Test that is the subject of the claim.

6.10 Nothing in the Contract limits or excludes the liability of Oncologica for breach of its obligations under section 12 of the Sale of Goods Act 1979 and/or section 2 of the Supply of Goods and Services Act 1982; death or personal injury resulting from negligence; or fraud or fraudulent misrepresentation.

6.11 If the Patient is a consumer (and not a business), the Patient expressly acknowledges and agrees that the Test is supplied to the Patient's specification and therefore there is no right to cancel the Test following acceptance under Clause 2.2. If the Patient is a consumer, then notwithstanding any other provisions of the Contract, none of the Patient's consumer statutory rights are affected.


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