

Medical Laboratory
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Leading a new era of precision oncology

Oncofocus®

Precision Oncology

Table of Contents	Page
Relevant Therapy Summary	3
Clinical Trials	5

Patient demographics

ONC19			
Surname		Requester	Self Referral
Forename		Contact details	
DOB		Date requested	
Gender			
Histology #		Tumour %	30
Primary site	Prostate	Tumour %	-
Tumour subtype	Adenocarcinoma	(macrodissected)	
Tissue Type	Prostate Biopsy		

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.

Oncofocus currently targets 505 genes covering oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors. Actionable genetic variants detected by Oncofocus are currently linked to 764 anti-cancer targeted therapies/therapy combinations.

The clinically significant bio-markers identified in this case are summarised on page 2

Please note: The assay detected a fusion; TMPRSS2 - ERG. There is currently no targeted therapies/therapy combinations linked to this fusion.

Within the 'Current Clinical Trials Information' section of this report, starting on page 5, the NCT numbers are hyperlinks to the clinicaltrials.gov webpages which should be accessed to gain further trial specific information

Clinically Significant Biomarkers

■ Indicated ■ Contraindicated

Genomic Alteration	Copy Number	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>ATM deletion</i>	0.85	Clinical trials and/or off-label	Clinical trials and/or off-label	13
<i>FANCD2 deletion</i>	0.3	Clinical trials and/or off-label	Clinical trials and/or off-label	8
<i>RB1 deletion</i>	0.4	Clinical trials and/or off-label	Clinical trials and/or off-label	2

Sources included in relevant therapies: EMA1, FDA2, ESMO, NCCN

Hotspot variants with >10% alternate allele reads are classified as 'detected' with an assay sensitivity and positive predictive value (PPV) of 99%. 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 >40 counts and meeting the thresholds of assay specific internal RNA quality control with a sensitivity of 92% and PPV of 99%. 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. Supplementary technical information is available upon request.

Lead Clinical Scientist: Keeda Hardisty

Clinical Scientist: Kaiya Chowdhary

Tier Criteria Met

Genomic Alteration	Tier Classification for Prostate Cancer
<i>ATM</i> deletion Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials
<i>FANCD2</i> deletion Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials
<i>RB1</i> deletion Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials

Reference: Li et al. *Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists.* J Mol Diagn. 2017 Jan;19(1):4-23.

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

ATM deletion					
Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
abiraterone acetate, enzalutamide, rucaparib	×	×	×	×	● (III)
abiraterone acetate + steroid, olaparib + abiraterone acetate + steroid	×	×	×	×	● (II)
durvalumab + olaparib	×	×	×	×	● (II)
olaparib	×	×	×	×	● (II)
olaparib + testosterone cypionate, olaparib + testosterone enanthate	×	×	×	×	● (II)
pembrolizumab	×	×	×	×	● (II)
pembrolizumab + chemotherapy	×	×	×	×	● (II)
rucaparib	×	×	×	×	● (II)
rucaparib + chemotherapy	×	×	×	×	● (II)
talazoparib	×	×	×	×	● (II)
avelumab + talazoparib	×	×	×	×	● (I/II)
BAY-1895344	×	×	×	×	● (I/II)
pamiparib + tislelizumab	×	×	×	×	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

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

FANCD2 deletion

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
durvalumab + olaparib	×	×	×	×	● (II)
olaparib + testosterone cypionate, olaparib + testosterone enanthate	×	×	×	×	● (II)
pembrolizumab	×	×	×	×	● (II)
pembrolizumab + chemotherapy	×	×	×	×	● (II)
prexasertib	×	×	×	×	● (II)
talazoparib	×	×	×	×	● (II)
avelumab + talazoparib	×	×	×	×	● (I/II)
BAY-1895344	×	×	×	×	● (I/II)

RB1 deletion

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
palbociclib	×	×	×	×	● (II)
prexasertib	×	×	×	×	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Relevant Therapy Details

Current Clinical Trials Information

Clinical Trials information is current as of 2019-03-01. 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'.

ATM deletion

NCT02975934

TRITON3: A Multicenter, Randomized, Open Label Phase III Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

Cancer type: Prostate Cancer

Variant class: HRR pathway

Other identifiers: 1723GCCC, CO-338-063, EudraCT Number: 2016-003163-20, GU 146, IGUP17020, IRAS ID: 222298, NCI-2017-01110, S16-02260, TRITON3

Population segments: First line, Hormone refractory, Stage IV

Phase: III

Therapies: abiraterone acetate, enzalutamide, rucaparib

Locations: Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Italy, Spain, United Kingdom, United States

US States: AL, AZ, CA, CO, CT, FL, HI, LA, MD, MI, MN, NC, NE, NV, NY, OH, OR, TN, TX, VA, WA

Contact: Clovis Oncology Clinical Trial Navigation Service [855-262-3040; clovistrials@emergingmed.com]

NCT03012321

BRCAAway: A Randomized Phase II Trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients With Metastatic Castration-Resistant Prostate Cancer With DNA Repair Defects

Cancer type: Prostate Cancer

Variant class: ATM deletion

Other identifiers: 19137, BRCAAway, NCI-2016-01834, NU 16U05, NU_16U05, PCCTC #: c16-168, STU00203960

Population segments: First line, Hormone refractory, Stage IV

Phase: II

Therapies: abiraterone acetate + steroid, olaparib + abiraterone acetate + steroid

Location: United States

US States: FL, IL, IN, MD, MI, MN, MO, NC, UT, VA

Contact: Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

ATM deletion (continued)

NCT03516812Bipolar Androgen Therapy Plus Olaparib
in Patient With Castration-Resistant
Prostate Cancer**Cancer type:** Prostate Cancer**Variant class:** DNA repair deletion**Other identifiers:** 9984, NCI-2018-00542, RG1718004**Population segments:** First line, Hormone refractory, Stage IV**Phase:** II**Therapies:** olaparib + testosterone cypionate, olaparib + testosterone enanthate**Location:** United States**US State:** WA**Contact:** Michael T. Schweizer [206-288-6252; schweize@uw.edu]**NCT03506997**PERSEUS1: Phase II Trial of the Immune
Checkpoint Inhibitor Pembrolizumab
for Patients Suffering From Metastatic
Prostate Cancer**Cancer type:** Prostate Cancer**Variant class:** DNA repair pathway**Other identifiers:** EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID
208952, PERSEUS1**Population segments:** Hormone refractory, Second line, Stage IV**Other inclusion criteria:** MMR deficient**Phase:** II**Therapy:** pembrolizumab**Location:** United Kingdom**NCT03248570**Phase II Open Label Study of
Pembrolizumab in Patients With
Metastatic Castration Resistant Prostate
Cancer (mCRPC) With or Without DNA
Damage Repair Defects**Cancer type:** Prostate Cancer**Variant class:** DNA repair pathway**Other identifiers:** 16557, 17-22165, CC 16557, NCI-2017-02408**Population segments:** Hormone refractory, Second line, Stage IV**Phase:** II**Therapy:** pembrolizumab + chemotherapy**Location:** United States**US State:** CA**Contact:** Paula Dutton [877-827-3222; cancertrials@ucsf.edu]

ATM deletion (continued)

NCT02952534

TRITON2: A Multicenter, Open-label Phase II Study of Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer Associated With Homologous Recombination Deficiency

Cancer type: Prostate Cancer

Variant class: HRR pathway

Other identifiers: 081704, 17-200, Clinical Trial 18986, CO-338-052, EudraCT Number:2016-003162-13, FVCTS-2017-25439, GU 142, IGUP17014, IRAS ID: 219516, NCI-2017-01109, P 36616, S16-01935, TRITON2, USO 16237

Population segments: Hormone refractory, Second line, Stage IV

Phase: II

Therapy: rucaparib

Locations: Australia, Belgium, Canada, Denmark, France, Germany, Ireland, Israel, Italy, Spain, United Kingdom, United States

US States: AL, AZ, CA, CO, CT, DC, FL, IL, LA, MD, MI, MN, MO, NE, NJ, NV, NY, OH, OR, TN, TX, VA, WA

Contact: Clovis Oncology Clinical Trial Navigation Service [855-262-3040; clovistrials@emergingmed.com]

NCT03442556

PLATI-PARP: A Phase II Study of Induction Docetaxel and Carboplatin Followed by Maintenance Rucaparib in Treatment of Patients With Metastatic Castration Resistant Prostate Cancer With Homologous Recombination DNA Repair Deficiency

Cancer type: Prostate Cancer

Variant class: HRR pathway

Other identifiers: 9841, NCI-2018-00016, PLATI-PARP

Population segments: Hormone refractory, Maintenance/Consolidation, Stage IV

Phase: II

Therapy: rucaparib + chemotherapy

Location: United States

US State: WA

Contact: Heather H. Cheng [206-606-1406; hhcheng@uw.edu]

NCT03330405

A Phase Ib/II Study To Evaluate Safety And Anti Tumor Activity Of Avelumab In Combination With The Poly(Adenosine Diphosphate [Adp]-Ribose) Polymerase (Parp) Inhibitor Talazoparib In Patients With Locally Advanced Or Metastatic Solid Tumors

Cancer type: Prostate Cancer

Variant class: ATM aberration

Other identifiers: 17-687, 18-1008, 2017-0524, 34807, B9991025, EudraCT Number: 2017-001509-33, IRAS ID 235395, JAVELIN PARP MEDLEY, NCI-2017-02385, s17-01353

Population segments: Estrogen receptor positive, HER2 negative, Hormone refractory, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: avelumab + talazoparib

Locations: Australia, Canada, Denmark, Hungary, Russian Federation, United Kingdom, United States

US States: AR, DC, MA, MN, NY, OH, TX

Contact: Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov_Inquiries@pfizer.com]

ATM deletion (continued)

NCT03188965

An Open-label, First-in-human, Dose-escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Maximum Tolerated Dose and / or Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Patients With Advanced Solid Tumors and Lymphomas

Cancer type: Prostate Cancer

Variant class: DNA repair pathway

Other identifiers: 18594, 2017-0186, BAY1895344/18594, EudraCT Number: 2016-004484-39, IRAS ID-218516, NCI-2018-00206, Trial ID: 16754

Population segments: Adenocarcinoma, Aggressive, Diffuse large B-cell lymphoma (DLBCL), Hormone refractory, Indolent, Mantle cell lymphoma (MCL), Second line, Squamous Cell, Stage III, Stage IV

Phase: I/II

Therapy: BAY-1895344

Locations: Canada, Singapore, Switzerland, United Kingdom, United States

US State: TX

Contact: Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

NCT02660034

A Phase I/Ib, Open Label, Multiple Dose, Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics and Antitumor Activity of the Anti-PD-1 Monoclonal Antibody BGB-A317 in Combination With the PARP Inhibitor BGB-290 in Subjects With Advanced Solid Tumors

Cancer type: Prostate Cancer

Variant class: HRR pathway

Other identifiers: 16-183, 18-009, A317/290, BGB-A317/BGB-290, BGB-A317/BGB-290_Study_001, CT783, NCI-2018-00791, P 55217, VICCPHI1814

Population segments: HER2 negative, Pulmonary, Second line, Stage III, Stage IV, Third line, Triple receptor negative

Phase: I

Therapy: pamiparib + tislelizumab

Locations: Australia, France, New Zealand, Spain, United Kingdom, United States

US States: AZ, CA, CO, FL, MA, NY, PA, TN, TX, VA

Contact: Rob Stewart [clinicaltrials@beigene.com]

No NCT ID - see other identifier(s)

Single Arm, Open label, Signal Seeking, Phase IIa Trial Of The Activity Of Olaparib In Combination With Durvalumab In Patients With Tumours With Homologous Recombination Repair Defects

Cancer type: Unspecified Solid Tumor

Variant class: ATM deletion

Other identifiers: ACTRN12617001000392, MoST Addendum 3, U1111-1182-6652

Population segments: Second line, Stage III, Stage IV

Phase: II

Therapy: durvalumab + olaparib

Location: Australia

ATM deletion (continued)

NCT02693535

Targeted Agent and Profiling Utilization
Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: ATM deletion

Other identifiers: 20170529, NCI-2017-00510, Pro00014171, TAPUR

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, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom's macroglobulinemia (WM)

Phase: II

Therapy: olaparib

Location: United States

US States: AL, AZ, CA, FL, GA, IL, MI, NC, ND, NE, OK, OR, PA, SD, TX, UT, VA, WA

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

NCT02286687

Phase II Study of the PARP Inhibitor BMN 673 (Talazoparib Tosylate) in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in PTEN or PTEN Loss, a Homologous Recombination Defect, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

Cancer type: Unspecified Cancer

Variant class: ATM deletion

Other identifiers: 2013-0961, NCI-2014-02494

Population segments: Fourth line or greater, Stage III, Stage IV

Phase: II

Therapy: talazoparib

Location: United States

US State: TX

Contact: Dr. Sarina Piha-Paul [713-563-1930]

FANCD2 deletion

NCT03516812

Bipolar Androgen Therapy Plus Olaparib in Patient With Castration-Resistant Prostate Cancer

Cancer type: Prostate Cancer

Variant class: DNA repair deletion

Other identifiers: 9984, NCI-2018-00542, RG1718004

Population segments: First line, Hormone refractory, Stage IV

Phase: II

Therapies: olaparib + testosterone cypionate, olaparib + testosterone enanthate

Location: United States

US State: WA

Contact: Michael T. Schweizer [206-288-6252; schweize@uw.edu]

FANCD2 deletion (continued)

NCT03506997

PERSEUS1: Phase II Trial of the Immune Checkpoint Inhibitor Pembrolizumab for Patients Suffering From Metastatic Prostate Cancer

Cancer type: Prostate Cancer

Variant class: DNA repair pathway

Other identifiers: EudraCT Number: 2017-000931-15, ICR-CTSU/2016/10060, IRAS ID 208952, PERSEUS1

Population segments: Hormone refractory, Second line, Stage IV

Other inclusion criteria: MMR deficient

Phase: II

Therapy: pembrolizumab

Location: United Kingdom

NCT03248570

Phase II Open Label Study of Pembrolizumab in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC) With or Without DNA Damage Repair Defects

Cancer type: Prostate Cancer

Variant class: DNA repair pathway

Other identifiers: 16557, 17-22165, CC 16557, NCI-2017-02408

Population segments: Hormone refractory, Second line, Stage IV

Phase: II

Therapy: pembrolizumab + chemotherapy

Location: United States

US State: CA

Contact: Paula Dutton [877-827-3222; cancertrials@ucsf.edu]

NCT03330405

A Phase Ib/II Study To Evaluate Safety And Anti Tumor Activity Of Avelumab In Combination With The Poly(Adenosine Diphosphate [Adp]-Ribose) Polymerase (Parp) Inhibitor Talazoparib In Patients With Locally Advanced Or Metastatic Solid Tumors

Cancer type: Prostate Cancer

Variant class: DNA repair pathway

Other identifiers: 17-687, 18-1008, 2017-0524, 34807, B9991025, EudraCT Number: 2017-001509-33, IRAS ID 235395, JAVELIN PARP MEDLEY, NCI-2017-02385, s17-01353

Population segments: Estrogen receptor positive, HER2 negative, Hormone refractory, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: avelumab + talazoparib

Locations: Australia, Canada, Denmark, Hungary, Russian Federation, United Kingdom, United States

US States: AR, DC, MA, MN, NY, OH, TX

Contact: Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov_Inquiries@pfizer.com]

FANCD2 deletion (continued)

NCT03188965

An Open-label, First-in-human, Dose-escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Maximum Tolerated Dose and / or Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Patients With Advanced Solid Tumors and Lymphomas

Cancer type: Prostate Cancer

Variant class: DNA repair pathway

Other identifiers: 18594, 2017-0186, BAY1895344/18594, EudraCT Number: 2016-004484-39, IRAS ID-218516, NCI-2018-00206, Trial ID: 16754

Population segments: Adenocarcinoma, Aggressive, Diffuse large B-cell lymphoma (DLBCL), Hormone refractory, Indolent, Mantle cell lymphoma (MCL), Second line, Squamous Cell, Stage III, Stage IV

Phase: I/II

Therapy: BAY-1895344

Locations: Canada, Singapore, Switzerland, United Kingdom, United States

US State: TX

Contact: Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

No NCT ID - see other identifier(s)

Single Arm, Open label, Signal Seeking, Phase IIa Trial Of The Activity Of Olaparib In Combination With Durvalumab In Patients With Tumours With Homologous Recombination Repair Defects

Cancer type: Unspecified Solid Tumor

Variant class: FANC deletion

Other identifiers: ACTRN12617001000392, MoST Addendum 3, U1111-1182-6652

Population segments: Second line, Stage III, Stage IV

Phase: II

Therapy: durvalumab + olaparib

Location: Australia

NCT02873975

A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency

Cancer type: Unspecified Solid Tumor

Variant class: Fanconi anemia pathway

Other identifiers: 16-281, I4D-MC-E006, NCI-2016-01564

Population segments: Second line, Stage III, Stage IV

Phase: II

Therapy: prexasertib

Location: United States

US State: MA

Contact: Dr. Geoffrey Shapiro [617-632-4942; Geoffrey_Shipiro@dfci.harvard.edu]

FANCD2 deletion (continued)**NCT02286687**

Phase II Study of the PARP Inhibitor BMN 673 (Talazoparib Tosylate) in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in PTEN or PTEN Loss, a Homologous Recombination Defect, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

Cancer type: Unspecified Cancer

Variant class: Fanconi anemia pathway

Other identifiers: 2013-0961, NCI-2014-02494

Population segments: Fourth line or greater, Stage III, Stage IV

Phase: II

Therapy: talazoparib

Location: United States

US State: TX

Contact: Dr. Sarina Piha-Paul [713-563-1930]

RB1 deletion**NCT02873975**

A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency

Cancer type: Unspecified Solid Tumor

Variant class: RB1 deletion

Other identifiers: 16-281, I4D-MC-E006, NCI-2016-01564

Population segments: Second line, Stage III, Stage IV

Phase: II

Therapy: prexasertib

Location: United States

US State: MA

Contact: Dr. Geoffrey Shapiro [617-632-4942; Geoffrey_S Shapiro@dfci.harvard.edu]

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, UPCC 03909, UPCC03909

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Metastatic, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line, Triple receptor negative

Phase: II

Therapy: palbociclib

Location: United States

US State: PA

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

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.

ATM deletion

Variant Class	Evidence Items
DNA repair pathway	7
↳ ATM aberration	1
↳ ATM deletion	4
↳ DNA repair deletion	2
↳ ATM deletion	4
HRR pathway	4
↳ ATM aberration	1
↳ ATM deletion	4

FANCD2 deletion

Variant Class	Evidence Items
DNA repair pathway	7
↳ DNA repair deletion	2
↳ FANCD2 deletion	0
Fanconi anemia pathway	2
↳ FANC deletion	1
↳ FANCD2 deletion	0

Evidence Summary by Variant Class (continued)

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.

RB1 deletion

Variant Class	Evidence Items
G1/S cell cycle pathway	1
↳ RB1 aberration	0
↳ RB1 deletion	1



oncologica®



Oncologica UK Ltd, Suite 2, The Newnham Building,
Chesterford Research Park, Little Chesterford, Cambridge,
CB10 1XL

+44 (0) 1223 785 327 - info@oncologica.com

Ireland

Bymac Centre, Northwest
Business Park, Blanchardstown, Dublin 15

+353 1 8604204

Italy

Parco Tecnologico della Sardegna
Pula, Località Piscinamanna

+39 02 808 88210