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 466 anti-cancer targeted therapies.

The following actionable variants were detected:

## Variant Summary

### Sample Cancer Type: Non-Small Cell Lung Cancer

<table>
<thead>
<tr>
<th>Gene Variant</th>
<th>EMA</th>
<th>US-FDA</th>
<th>ESMO</th>
<th>US-NCCN</th>
<th>Global Clinical Trials</th>
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<tbody>
<tr>
<td>PTEN p.(V166fs) c.497_513delTAACTATTCCAGTCAG</td>
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<td>TP53 p.(V157F) c.469G&gt;T</td>
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<td>FBXW7 p.(R441W) c.1321C&gt;T</td>
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**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

PTEN p.(V166fs) c.497_513delTAATATTCCCAGTCAG

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<th>Relevant Therapy</th>
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<td>olaparib + vistusertib</td>
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<td>(II)</td>
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<tr>
<td>selumetinib + vistusertib</td>
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<tr>
<td>AZD-5363</td>
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<tr>
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TP53 p.(V157F) c.469G>T

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<th>ESMO</th>
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<th>Global Clinical Trials*</th>
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<td>ixazomib + vorinostat</td>
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<td>MK-1775</td>
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<td>X</td>
<td>(I)</td>
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<tr>
<td>pembrolizumab + p53MVA</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>(I)</td>
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</tbody>
</table>

* 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.

ONC17-: www.oncologica.com

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### TP53 p.(V157F) c.469G>T (continued)

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<th>Relevant Therapy</th>
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<td>✗</td>
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<tr>
<td>VX-970 + chemotherapy</td>
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### FBXW7 p.(R441W) c.1321C>T

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<tbody>
<tr>
<td>palbociclib</td>
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<td>prexasertib</td>
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<td>⚪ (II)</td>
</tr>
</tbody>
</table>

* 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.
## 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’.

### NCT02583542
A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers.

**Cancer type:** Non-Small Cell Lung Cancer  
**Variant class:** PI3K/AKT/MTOR pathway  
**Other identifiers:** 009896OM, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcmek, TrialTroveID-265019, UKCRN ID:18725  
**Population segments:** EGFR, FGFR, HER2 negative, HER2 positive, KRAS, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative  
**Phase:** I/II  
**Therapy:** selumetinib + vistusertib  
**Location:** United Kingdom  

### NCT01655225
A Phase I First-in-Human Dose Study of LY3023414 in Patients With Advanced Cancer.

**Cancer type:** Non-Small Cell Lung Cancer  
**Variant class:** PI3K/AKT/MTOR pathway  
**Other identifiers:** 12-286, 13517, I6A-MC-CBBA, REFMAL 276, TrialTroveID-172222  
**Population segments:** Estrogen receptor positive, Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), HER2 negative, Indolent, Other subtype, Progesterone receptor positive, Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Squamous Cell, Stage III, Stage IV, Untreated, Waldenstrom’s macroglobulinemia (WM)  
**Phase:** I  
**Therapies:** LY-3023414, LY-3023414 + midazolam  
**Locations:** Italy, United States  
**US States:** NY, OK, PA, TN  
**US Contact:** Eli Lilly and Company [877-285-4559]  

### PTEN p.(V166fs) c.497_513delTAACTATTCAGTCAG

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PTEN p.(V166fs) c.497_513delTAACATTATTCAGTCAG (continued)

**NCT02029001**
A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients With Progressive Locally-advanced or Metastatic Solid Tumors MOST: My own specific treatment

- **Cancer type:** Unspecified Solid Tumor
- **Variant class:** PTEN mutation
- **Other identifiers:** ET12-081, EudraCT number: 2012-004510-34, MOST, Profiler, TrialTroveID-200294
- **Population segments:** Maintenance/Consolidation, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
- **Phase:** II
- **Therapy:** everolimus
- **Location:** France

**NCT02465060**
Molecular Analysis for Therapy Choice (MATCH)

- **Cancer type:** Unspecified Solid Tumor
- **Variant class:** PTEN mutation
- **Population segments:** (N/A), Aggressive, ALK, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
- **Other inclusion criteria:** PTEN expression
- **Phase:** II
- **Therapy:** GSK-2636771
- **Location:** United States
- **US States:** AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WI, WV, WY
- **US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG (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

- **Variant class**: PTEN mutation
- **Other identifiers**: 1508016363, OLAPCO, TrialTroveID-266161
- **Population segments**: First line, Second line or greater/Refractory/Relapsed, Stage IV
- **Phase**: II
- **Therapy**: olaparib + vistusertib
- **Location**: United States
- **US States**: CT, MA
- **US Contact**: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

**NCT01884285**
A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Anti-tumour Activity of AZD8186 in Patients with Advanced Castration-resistant Prostate Cancer (CRPC), Squamous Non-Small Cell Lung Cancer (sqNSCLC), Triple Negative Breast Cancer (TNBC) and Patients with Known PTEN-deficient/mutated or PIK3CB mutated/ amplified Advanced Solid Malignancies as Monotherapy and in Combination with Abiraterone Acetate or AZD2014

- **Variant class**: PTEN mutation
- **Other identifiers**: 13-300, 20131275, D4620C00001, EudraCT Number: 2013-000703-17, IRAS ID: 129536, NCI-2013-02191, TrialTroveID-189056
- **Population segments**: HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative
- **Phase**: I
- **Therapies**: AZD8186, AZD8186 + abiraterone acetate + prednisone, AZD8186 + vistusertib
- **Locations**: Canada, Spain, United Kingdom, United States
- **US States**: MA, MI, WA, WI
- **US Contact**: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]
PTEN p.(V166fs) c.497_513delTAACTATTCCAGTCAG (continued)

NCT01971515
A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects With Advanced Malignancies
Cancer type: Unspecified Solid Tumor
Variant class: PTEN aberration

Other identifiers: 2013-0525, CHRMS 14-081, EMR100018-001, NCI-2013-02370, TrialTroveID-196334
Population segments: Aggressive, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Exclusion criteria variant classes: AKT2 amplification, AKT2 mutation
Phase: I
Therapy: MSC-2363318A
Location: United States
US States: AL, CA, FL, MI, NY, TX, VT
US Contact: US Medical Information [888-275-7376]

NCT01226316
A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD5363 Under Adaptable Dosing Schedules in Patients with Advanced Solid Malignancies
Cancer type: Unspecified Solid Tumor
Variant class: PI3K/AKT/MTOR pathway

Population segments: Adenocarcinoma, Estrogen receptor positive, HER2 positive, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Exclusion criteria variant classes: BRAF mutation, HRAS mutation, KRAS mutation, NRAS mutation
Phase: I
Therapy: AZD-5363
Locations: Canada, Denmark, France, Italy, Japan, Netherlands, Singapore, Spain, United States
US States: CA, CO, CT, NY, OK, PA, SC, TN, TX
US Contact: AstraZeneca Clinical Study Information [877-240-9479; information.center@astrazeneca.com]

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PTEN p.(V166fs) c.497_513delTAACTATTCCAGTCAG (continued)

NCT02338622
A Phase I Multi-centre Trial of the Combination of Olaparib (PARP Inhibitor) and AZD5363 (AKT Inhibitor) in Patients With Advanced Solid Tumours
Cancer type: Unspecified Solid Tumor
Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 14/LO/0103, CCR4058, ComPAKT, CRUKD/14/004, EudraCT number: 2013-004692-13, TrialTroveID-213474, UKCRN ID 16550
Population segments: HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative
Phase: I
Therapy: AZD-5363 + olaparib
Location: United Kingdom

NCT02389842
PIPA: A Phase Ib Study to Assess the Safety, Tolerability and Efficacy of the PI3K Inhibitors, Taselisib (GDC-0032) or Pictilisib (GDC-0941), in Combination With PAlbociclib, With the Subsequent Addition of Fulvestrant in PIK3CA-mutant Breast Cancers
Cancer type: Unspecified Solid Tumor
Variant class: PI3K/AKT/MTOR pathway

Other identifiers: CCR4191, EudraCT Number: 2014-002658-37, IRAS ID 159997, PIPA, TrialTroveID-253778
Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: I
Therapies: palbociclib + pictilisib, palbociclib + taselisib
Location: United Kingdom

NCT02483858
Phase I Study of Oral PQR309 in Patients With Advanced Solid Tumors.
Cancer type: Unspecified Solid Tumor
Variant class: PI3K/AKT/MTOR pathway

Other identifiers: EudraCT Number: 2015-003919-38, I 258914, IRAS ID: 193390, PQR309-003, REec-2016-2264, TrialTroveID-260655
Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: I
Therapy: PQR-309
Location: United States
US State: NY
US Contact: Dr. Alex Adjei [Alex.Adjei@RoswellPark.org]

DISCLAIMER: The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2017.03(003).
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<thead>
<tr>
<th>Study ID</th>
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<tr>
<td>NCT02299141</td>
<td>A Pilot Study of Nintedanib in Molecularly Selected Patients With Advanced Non-Small Cell Lung Cancer (NSCLC)</td>
<td>Non-Small Cell Lung Cancer</td>
<td>TP53 mutation</td>
<td>14-x346, 201412116, NCI-2014-02625, TrialTroveID-218546</td>
<td>FGFR, First line, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
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<td>nintedanib</td>
<td>United States</td>
<td>MO</td>
<td>Dr. Ramaswamy Govindan [314-362-5654; <a href="mailto:rgovindan@wustl.edu">rgovindan@wustl.edu</a>]</td>
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<tr>
<td>NCT02193152</td>
<td>A Pilot Study of Pazopanib in Molecularly Selected Patients With Advanced Non-Small Cell Lung Cancer (NSCLC)</td>
<td>Non-Small Cell Lung Cancer</td>
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<td>First line, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
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<td>pazopanib</td>
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<td>MO</td>
<td>Dr. Daniel Morgensztern [314-362-5737; <a href="mailto:danielmorgensztern@wustl.edu">danielmorgensztern@wustl.edu</a>]</td>
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<td>NCT02432963</td>
<td>A Phase I Study of a p53MVA Vaccine in Combination With Pembrolizumab</td>
<td>Non-Small Cell Lung Cancer</td>
<td>TP53 mutation</td>
<td>116634, 122284, 122771, 124524, 15002, NCI-2015-00653, TrialTroveID-256830</td>
<td>HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative, Unresectable</td>
<td>I</td>
<td>pembrolizumab + p53MVA</td>
<td>United States</td>
<td>CA</td>
<td>Vincent Chung [800-826-4673]</td>
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### NCT02157792

**Study Title:** An Open-Label, First-in-Human Study of the Safety, Tolerability, and Pharmacokinetics of VX-970 in Combination With Cytotoxic Chemotherapy in Subjects With Advanced Solid Tumors  
**Cancer type:** Non-Small Cell Lung Cancer  
**Variant class:** TP53 mutation  
**Other identifiers:** 112876, 14-040, EudraCT Number: 2012-003126-25, NCI-2014-02042, OSU-13211, TrialTroveID-190735, VICCBRE1587, VX12-970-001  
**Population segments:** First line, HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative  
**Phase:** I  
**Therapy:** VX-970 + chemotherapy  
**Locations:** United Kingdom, United States  
**US States:** CA, CO, GA, IL, MA, MI, MO, NY, OH, SC, TN, TX, VA, WA  
**US Contact:** Medical Monitor [617-341-6777; medicalinfo@vrtx.com]

### NCT02576444

**Study Title:** 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  
**Location:** United States  
**US States:** CT, MA  
**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

### NCT02042989

**Study Title:** 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  
**Location:** United States  
**US State:** TX  
**US Contact:** Dr. Siqing Fu [713-563-1930]

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### TP53 p.(V157F) c.469G>T (continued)

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<th>Other identifiers: D6015C00003, REFMAL 398, TrialTroveID-268385</th>
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<td><strong>A Phase Ib Study to Determine the Maximum Tolerated Dose (MTD) of AZD1775 Monotherapy in Patients With Locally Advanced or Metastatic Solid Tumours.</strong></td>
<td><strong>Population segments:</strong> Liver mets, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
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<tr>
<td><strong>Cancer type:</strong> Unspecified Solid Tumor</td>
<td><strong>Phase:</strong> I</td>
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<tr>
<td><strong>Variant class:</strong> TP53 mutation</td>
<td><strong>Therapy:</strong> MK-1775</td>
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<td><strong>Location:</strong> United States</td>
<td><strong>US States:</strong> CO, TN</td>
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<tr>
<td><strong>US Contact:</strong> AstraZeneca Clinical Study Information Center [877-240-9479; <a href="mailto:information.center@astrazeneca.com">information.center@astrazeneca.com</a>]</td>
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<table>
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<th>Other identifiers: 1405-1316, SGT53-01-2, TrialTroveID-251586</th>
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<tr>
<td><strong>A Phase I Study of SGT-53, a TfRscFv-Liposome-p53 Complex, in Children with Refractory or Recurrent Solid Tumors</strong></td>
<td><strong>Population segments:</strong> (N/A), Second line or greater/Refractory/Relapsed</td>
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<tr>
<td><strong>Cancer type:</strong> Unspecified Solid Tumor</td>
<td><strong>Phase:</strong> I</td>
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<tr>
<td><strong>Variant class:</strong> TP53 mutation</td>
<td><strong>Therapies:</strong> SGT-53, SGT-53 + chemotherapy</td>
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<td><strong>Location:</strong> United States</td>
<td><strong>US State:</strong> TX</td>
</tr>
<tr>
<td><strong>US Contact:</strong> Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
<td></td>
</tr>
</tbody>
</table>

### FBXW7 p.(R441W) c.1321C>T

<table>
<thead>
<tr>
<th>NCT02873975</th>
<th>Other identifiers: 16-281, TrialTroveID-284902</th>
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<tbody>
<tr>
<td><strong>A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency</strong></td>
<td><strong>Population segments:</strong> Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
</tr>
<tr>
<td><strong>Cancer type:</strong> Unspecified Solid Tumor</td>
<td><strong>Phase:</strong> II</td>
</tr>
<tr>
<td><strong>Variant class:</strong> FBXW7 mutation</td>
<td><strong>Therapy:</strong> prexasertib</td>
</tr>
<tr>
<td><strong>Location:</strong> United States</td>
<td><strong>US State:</strong> MA</td>
</tr>
<tr>
<td><strong>US Contact:</strong> Dr. Geoffrey Shapiro [617-632-4942; <a href="mailto:Geoffrey_Shapiro@dfci.harvard.edu">Geoffrey_Shapiro@dfci.harvard.edu</a>]</td>
<td></td>
</tr>
</tbody>
</table>

**ONC17-:** www.oncologica.com

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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### FBXW7 p.(R441W) c.1321C>T (continued)

<table>
<thead>
<tr>
<th>NCT01037790</th>
<th>Other identifiers: NCI-2009-01467, Study 1006, TrialTrivelD-120590, UPCC 03909, UPCC03909</th>
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<tbody>
<tr>
<td>Phase II Trial of the Cyclin-Dependent Kinase Inhibitor PD 0332991 in Patients With Cancer</td>
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</tr>
<tr>
<td>Cancer type: Unspecified Solid Tumor</td>
<td>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</td>
</tr>
<tr>
<td>Variant class: G1/S cell cycle pathway</td>
<td>Phase: II</td>
</tr>
<tr>
<td></td>
<td>Therapy: palbociclib</td>
</tr>
<tr>
<td></td>
<td>Location: United States</td>
</tr>
<tr>
<td></td>
<td>US State: PA</td>
</tr>
<tr>
<td></td>
<td>US Contact: Peter O'Dwyer [855-216-0098; <a href="mailto:PennCancerTrials@emergingmed.com">PennCancerTrials@emergingmed.com</a>]</td>
</tr>
</tbody>
</table>

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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.

<table>
<thead>
<tr>
<th>Variant Class</th>
<th>Evidence Items</th>
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</thead>
<tbody>
<tr>
<td>PI3K/AKT/MTOR pathway</td>
<td>6</td>
</tr>
<tr>
<td>↔ PTEN aberration</td>
<td>1</td>
</tr>
<tr>
<td>↔ PTEN mutation</td>
<td>4</td>
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</table>

<table>
<thead>
<tr>
<th>Variant Class</th>
<th>Evidence Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>TP53 mutation</td>
<td>8</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Variant Class</th>
<th>Evidence Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1/S cell cycle pathway</td>
<td>1</td>
</tr>
<tr>
<td>↔ FBXW7 mutation</td>
<td>1</td>
</tr>
</tbody>
</table>
## Appendix: Variant Details

### DNA Sequence Variants

<table>
<thead>
<tr>
<th>Gene</th>
<th>Amino Acid Change</th>
<th>Coding</th>
<th>Variant ID</th>
<th>Locus</th>
<th>Allele Frequency</th>
<th>Transcript</th>
<th>Variant Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBXW7</td>
<td>p.(R441W)</td>
<td>c.1321C&gt;T</td>
<td>chr4:153249457</td>
<td>13.16%</td>
<td>NM_033632.3</td>
<td>missense</td>
<td></td>
</tr>
<tr>
<td>PTEN</td>
<td>p.(V166fs)</td>
<td>c.497_513delTAACATTCCAGTCAG</td>
<td>chr10:89711876</td>
<td>23.57%</td>
<td>NM_000314.4</td>
<td>frameshift Deletion</td>
<td></td>
</tr>
<tr>
<td>TP53</td>
<td>p.(V157F)</td>
<td>c.469G&gt;T</td>
<td>COSM10670</td>
<td>chr17:7578461</td>
<td>15.30%</td>
<td>NM_000546.5</td>
<td>missense</td>
</tr>
</tbody>
</table>

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Terms and Conditions

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 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.

6.5 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.

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Chesterford Research Park
Cambridge, CB10 1XL, UK
Tel: +44(0)1223 785327
Email: info@oncologica.com

Terms and Conditions, once a contract comes into existence as per paragraph 2 of the Oncologica Test's Terms and Conditions.
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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