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>
<td>x</td>
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<td>x</td>
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<tr>
<td>TP53 p.(V157F) c.469G&gt;T</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>(8)</td>
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<tr>
<td>FBXW7 p.(R441W) c.1321C&gt;T</td>
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<td>x</td>
<td>x</td>
<td>x</td>
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</table>

**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.

**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).
**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

### PTEN p.(V166fs) c.497_513delTAATTTAATTCAGTCAG

<table>
<thead>
<tr>
<th>Relevant Therapy</th>
<th>EMA</th>
<th>US-FDA</th>
<th>ESMO</th>
<th>US-NCCN</th>
<th>Global Clinical Trials*</th>
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<td>✗</td>
<td>✗</td>
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<tr>
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<tr>
<td>olaparib + vistusertib</td>
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<td>✗</td>
<td>✗</td>
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<td></td>
</tr>
<tr>
<td>selumetinib + vistusertib</td>
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<td>✗</td>
<td>✗</td>
<td></td>
<td>(I/II)</td>
</tr>
<tr>
<td>AZD-5363</td>
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<td>✗</td>
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<tr>
<td>AZD-5363 + olaparib</td>
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<td>✗</td>
<td></td>
<td>(I)</td>
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<tr>
<td>AZD8186, AZD8186 + abiraterone acetate + prednisone, AZD8186 + vistusertib</td>
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<td>LY-3023414, LY-3023414 + midazolam</td>
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<td>✗</td>
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### TP53 p.(V157F) c.469G>T

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<th>ESMO</th>
<th>US-NCCN</th>
<th>Global Clinical Trials*</th>
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<tbody>
<tr>
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<td>✗</td>
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<td>MK-1775</td>
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<td>pembrolizumab + p53MVA</td>
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<td></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.

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Relevant Therapy Summary (continued)

<table>
<thead>
<tr>
<th>Relevant Therapy</th>
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<th>ESMO</th>
<th>US-NCCN</th>
<th>Global Clinical Trials*</th>
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<td>(I)</td>
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<tr>
<td>VX-970 + chemotherapy</td>
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</table>

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

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

<table>
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<tr>
<th>Relevant Therapy</th>
<th>EMA</th>
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<th>Global Clinical Trials*</th>
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</thead>
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<td>(II)</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.
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’.

PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG

| NCT02583542 | Other identifiers: 0098960M, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcemk, 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
| Cancer type: Non-Small Cell Lung Cancer
| Phase: I/II
| Therapies: selumetinib + vistusertib
| Location: United Kingdom

| NCT01655225 | 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)
| Cancer type: Non-Small Cell Lung Cancer
| 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_513delTAACATTATCCAGTCAG (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Other identifiers</th>
<th>Cancer type</th>
<th>Variant class</th>
<th>Population segments</th>
<th>Phase</th>
<th>Therapy</th>
<th>Location</th>
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<tbody>
<tr>
<td>NCT02029001</td>
<td>ET12-081, EudraCT number: 2012-004510-34, MOST, ProfiLER, TrialTroveID-200294</td>
<td>Unspecified Solid Tumor</td>
<td>PTEN mutation</td>
<td>Maintenance/Consolidation, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
<td>II</td>
<td>everolimus</td>
<td>France</td>
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</tbody>
</table>

**Other inclusion criteria:** PTEN expression

**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_513delTAACTATTCCAGTCAG (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
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<th>Phase</th>
<th>Therapy</th>
<th>Location</th>
<th>US States</th>
<th>US Contact</th>
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</thead>
<tbody>
<tr>
<td>NCT02576444</td>
<td>1508016363, OLAPCO, TrialTroveID-266161</td>
<td>First line, Second line or greater/Refractory/Relapsed, Stage IV</td>
<td>II</td>
<td>olaparib + vistusertib</td>
<td>United States</td>
<td>CT, MA</td>
<td>Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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<tr>
<td>NCT01884285</td>
<td>13-300, 20131275, D4620C00001, EudraCT Number: 2013-000703-17, IRAS ID: 129536, NCI-2013-02191, TrialTroveID-189056</td>
<td>HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative</td>
<td>I</td>
<td>AZD8186, AZD8186 + abiraterone acetate + prednisone, AZD8186 + vistusertib</td>
<td>Canada, Spain, United Kingdom, United States</td>
<td>MA, MI, WA, WI</td>
<td>AstraZeneca Clinical Study Information Center [877-240-9479; <a href="mailto:information.center@astrazeneca.com">information.center@astrazeneca.com</a>]</td>
</tr>
</tbody>
</table>

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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<table>
<thead>
<tr>
<th>Study ID</th>
<th>Phase</th>
<th>Variant class</th>
<th>Cancer type</th>
<th>Other identifiers</th>
<th>Population segments</th>
<th>Exclusion criteria variant classes</th>
<th>Therapy</th>
<th>Location</th>
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</thead>
<tbody>
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<td>NCT01971515</td>
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<td>PTEN aberration</td>
<td>Unspecified Solid Tumor</td>
<td>2013-0525, CHRS 14-081, EMR100018-001, NCI-2013-02370, TrialTroveID-196334</td>
<td>Aggressive, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
<td>AKT2 amplification, AKT2 mutation</td>
<td>MSC-2363318A</td>
<td>United States</td>
<td>AL, CA, FL, MI, NY, TX, VT</td>
<td>US Medical Information [888-275-7376]</td>
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<tr>
<td>NCT01226316</td>
<td>I</td>
<td>PI3K/AKT/MTOR pathway</td>
<td>Unspecified Solid Tumor</td>
<td>102084, 14-214, 14-430, 2014-0160, CR1322AZ, D3610C00001, EudraCT Number: 2010-022167-35, IRAS ID: 62131, JapicCTI-152844, M10AZD, NCI-2014-01803, NL33755.031.10, P1TGIVEN, TrialTroveID-136773</td>
<td>Adenocarcinoma, Estrogen receptor positive, HER2 positive, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
<td>BRAF mutation, HRAS mutation, KRAS mutation, NRAS mutation</td>
<td>AZD-5363</td>
<td>Canada, Denmark, France, Italy, Japan, Netherlands, Singapore, Spain, United States</td>
<td>CA, CO, CT, NY, OK, PA, SC, TN, TX</td>
<td>AstraZeneca Clinical Study Information [877-240-9479; <a href="mailto:information.center@astrazeneca.com">information.center@astrazeneca.com</a>]</td>
</tr>
</tbody>
</table>
PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG (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]
TP53 p.(V157F) c.469G>T

NCT02299141
A Pilot Study of Nintedanib in Molecularly Selected Patients With Advanced Non-Small Cell Lung Cancer (NSCLC)

Cancer type: Non-Small Cell Lung Cancer
Variant class: TP53 mutation

Other identifiers: 14-x346, 2014122116, NCI-2014-02625, TrialTroveID-218546
Population segments: FGFR, First line, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: II
Therapy: nintedanib
Location: United States
US State: MO
US Contact: Dr. Ramaswamy Govindan [314-362-5654; rgovindan@wustl.edu]

NCT02193152
A Pilot Study of Pazopanib in Molecularly Selected Patients With Advanced Non-Small Cell Lung Cancer (NSCLC)

Cancer type: Non-Small Cell Lung Cancer
Variant class: TP53 mutation

Other identifiers: 14-X182, 201408009, 201566, NCI-2014-01760, PRMC 14-X182, TrialTroveID-213213
Population segments: First line, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: II
Therapy: pazopanib
Location: United States
US State: MO
US Contact: Dr. Daniel Morgensztern [314-362-5737; danielmorgensztern@wustl.edu]

NCT02432963
A Phase I Study of a p53MVA Vaccine in Combination With Pembrolizumab

Cancer type: Non-Small Cell Lung Cancer
Variant class: TP53 mutation

Other identifiers: 116634, 122284, 122771, 124524, 15002, NCI-2015-00653, TrialTroveID-256830
Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative, Unresectable
Phase: I
Therapy: pembrolizumab + p53MVA
Location: United States
US State: CA
US Contact: Vincent Chung [800-826-4673]

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

**NCT02157792**
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**
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**
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]

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

<table>
<thead>
<tr>
<th>Trial Identifier</th>
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<tr>
<td>NCT02610075</td>
<td>A Phase Ib Study to Determine the Maximum Tolerated Dose (MTD) of AZD1775 Monotherapy in Patients With Locally Advanced or Metastatic Solid Tumours.</td>
</tr>
<tr>
<td>NCT02354547</td>
<td>A Phase I Study of SGT-53, a TfRscFv-Liposome-p53 Complex, in Children with Refractory or Recurrent Solid Tumors</td>
</tr>
<tr>
<td>NCT02873975</td>
<td>A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency</td>
</tr>
</tbody>
</table>

**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

**Location:** United States

**US States:** CO, TN

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

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

<table>
<thead>
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<th>Trial Identifier</th>
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<tr>
<td>NCT02873975</td>
<td>A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency</td>
</tr>
</tbody>
</table>

**Other identifiers:** 16-281, TrialTroveID-284902

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

**Phase:** II

**Therapy:** prexasertib

**Location:** United States

**US State:** MA

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

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FBXW7 p.(R441W) c.1321C>T (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]
Appendix: Evidence Summary by Variant Class

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

<table>
<thead>
<tr>
<th>Variant Class</th>
<th>Evidence Items</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG</strong></td>
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<tr>
<td>PI3K/AKT/MTOR pathway</td>
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<td>➤ PTEN aberration</td>
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<tr>
<td>➤ PTEN mutation</td>
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<thead>
<tr>
<th>Variant Class</th>
<th>Evidence Items</th>
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<tr>
<td><strong>TP53 p.(V157F) c.469G&gt;T</strong></td>
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<tr>
<td>TP53 mutation</td>
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</table>

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<thead>
<tr>
<th>Variant Class</th>
<th>Evidence Items</th>
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<tbody>
<tr>
<td><strong>FBXW7 p.(R441W) c.1321C&gt;T</strong></td>
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<tr>
<td>G1/S cell cycle pathway</td>
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<td>➤ FBXW7 mutation</td>
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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.

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).
### 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 Transcript</th>
<th>Variant Effect</th>
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<tbody>
<tr>
<td>FBXW7</td>
<td>p.(R441W)</td>
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<td>chr4:153249457</td>
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<tr>
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<td>COSM10670</td>
<td>chr17:7578461</td>
<td>15.30% NM_000546.5</td>
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</table>

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