NEOADJUVANT THERAPY

HR-positive
HER2-negative

IRB# 6256
ISPY-2: Neoadjuvant and Personalized Adaptive Novel Agents

IRB# 21243
Neoadjuvant Abemaciclib and Niraparib

IRB# 22191
Keynote-756: Pembrolizumab/Placebo in combo with neoadjuvant chemotherapy & Adjuvant Endocrine Therapy

HER2-positive

IRB# 6256
ISPY-2: Neoadjuvant and Personalized Adaptive Novel Agents

Triple Negative

IRB# 6256
ISPY-2: Neoadjuvant and Personalized Adaptive Novel Agents

http://www.ohsu.edu/research/rda-so/knight.php

Key

- Open for Enrollment
- In Development
- Enrollment on Hold

29 Dec 2020
BREAST CANCER

ADJUVANT THERAPY

HR-positive HER2-negative

IRB#22395
DARE: DNA-Guided Second Line Adjuvant Therapy For High Residual Risk, Stage II-III

HER2-positive

No trial currently available

Triple Negative

IRB#17461
SWOG S1418: Pembrolizumab as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer

IRB#22388
Ipi/Nivo/Cryo: Peri-Operative Iplilimumab+Nivolumab and Cryoablation Versus Standard Care

http://www.ohsu.edu/research/rda/so/knight.php
BREAST CANCER

METASTATIC THERAPY

HR-positive
HER2-negative

ENDOCRINE

Physician’s Choice

CHEMO

1L

No trial currently available

2L

IRB#22225
OP-1250-001: A Dose Escalation/Expansion study of OP-1250

IRB#20440
CT7001-001: CT7001 Alone and in Combination with Anti-Cancer Treatments

IRB#21441
EA1183: FDG-PET/CT

IRB#17887
SGNLIVA-001: (Part E) A Safety Study of SGN-LIV1a

>2L

IRB#22225
OP-1250-001: A Dose Escalation/Expansion study of OP-1250

http://www.ohsu.edu/research/rda/so/knight.php
BREAST CANCER

METASTATIC THERAPY

1L

IRB#20112
HER2CLIMB-02: T-DM1 and Tucatinib/Placebo

IRB#21441
EA1183: FDG-PET/CT

IRB#19078
S1501: Carvediol in Preventing Cardiac Toxicity

2L

IRB#20112
HER2CLIMB-02: T-DM1 and Tucatinib/Placebo

IRB#19830
TDM1 +/- Palbociclib

IRB#21441
EA1183: FDG-PET/CT

IRB#19078
S1501: Carvediol in Preventing Cardiac Toxicity

>2L

IRB#19078
S1501: Carvediol in Preventing Cardiac Toxicity

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BREAST CANCER

METASTATIC THERAPY

Triple Negative

1L

IRB#18504
AMTEC: Olaparib + Durvalumab

2L

IRB#18504
AMTEC: Olaparib + Durvalumab

IRB#17887
SGNLVA-001: (Part E) A Safety Study of SGN-LIV1a

>2L

IRB#18504
AMTEC: Olaparib + Durvalumab

http://www.ohsu.edu/research/rda/so/knight.php

Key
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29 Dec 2020
<table>
<thead>
<tr>
<th>IRB#</th>
<th>Title</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>15588</td>
<td>SMMART-PRIME</td>
<td>Heavily Pre-treated, HR+HER2-, HER2+, TNBC</td>
</tr>
<tr>
<td>20679</td>
<td>SMMART-ACT</td>
<td>HR+HER2-, HER2+, TNBC, Pre-screen (molecular target)</td>
</tr>
<tr>
<td>19904</td>
<td>NEO-RAY (Nuc Med)</td>
<td>Heavily Pre-treated, Pre-screen required</td>
</tr>
<tr>
<td>19992</td>
<td>EAY131 (MATCH)</td>
<td>Pre-screen (molecular target)</td>
</tr>
<tr>
<td>18084</td>
<td>S1609 (DART)</td>
<td>Pre-screen (rare molecular target)</td>
</tr>
<tr>
<td>19489</td>
<td>(Lutathera IIT)</td>
<td>Targeting Metastatic Breast Cancer and Breast Cancer Stem Cells with Lutathera</td>
</tr>
<tr>
<td>16676</td>
<td>BLU-667 (Phase 1)</td>
<td>Advanced solid tumor with oncogenic RET fusion (expected to close soon)</td>
</tr>
<tr>
<td>18164</td>
<td>Loxo RET (Phase 1)</td>
<td>RET fusion-positive</td>
</tr>
</tbody>
</table>

http://www.ohsu.edu/research/rda/so/knight.php
**CROSS-DISEASE TRIALS**

Continued

<table>
<thead>
<tr>
<th>IRB#21349</th>
<th>MORAB-202 (Phase 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>TNBC</strong>: Previously treated (cytotoxic or targeted anticancer agents) in the metastatic setting.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IRB#21766</th>
<th>GEN001 (Phase 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patients must have progressed on at least two lines of approved therapy for their histological subtype</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IRB# 21508</th>
<th>ORIC-101 (Phase 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>TNBC</strong> with no alternative effective standard therapy</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IRB#21548</th>
<th>AMG 650 (Phase 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>TNBC</strong> relapsed/refractory to at least one line of systemic chemotherapy in the metastatic setting or intolerant of existing therapy(ies).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IRB#21819</th>
<th>ASTX029 (Phase 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Phase 1B</strong>: documented activating gene mutations in BRAF (BRAF V600 mutation or activating atypical non-V600 aberrations), KRAS, NRAS, or HRAS</td>
<td></td>
</tr>
</tbody>
</table>

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1 To inquire about Phase 1 trial open slots please contact stadnik@ohsu.edu.

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1 29 Dec 2020

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