BREAST CANCER

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
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 Ipilimumab+Nivolumab and Cryoablation Versus Standard Care**

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BREAST CANCER

METASTATIC THERAPY

1L
IRB#22730
SERENA-4: AZD9833 with palbociclib vs. anastrozole with palbociclib

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

>2L
IRB#22225
OP-1250-001: A Dose Escalation/Expansion study of OP-1250

HR-positive HER2-negative

Physician’s Choice

CHEMO

No trial currently available

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METASTATIC THERAPY

1L
- IRB#20112 HER2CLIMB-02: T-DM1 and Tucatinib/Placebo
- IRB#19830 HER2CLIMB-02: T-DM1 and Tucatinib/Placebo

2L
- IRB#20112 HER2CLIMB-02: T-DM1 and Tucatinib/Placebo
- IRB#19830 HER2CLIMB-02: T-DM1 and Tucatinib/Placebo
- IRB#21441 EA1183: FDG-PET/CT

>2L
- IRB#19078 S1501: Carvediol in Preventing Cardiac Toxicity
- IRB#21441 EA1183: FDG-PET/CT
- 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

>2L
IRB#18504
AMTEC: Olaparib + Durvalumab

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

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

Key:
- Open for Enrollment
- In Development
- Enrollment on Hold

15 Mar 2021
## CROSS-DISEASE TRIALS

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

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15 Mar 2021
<table>
<thead>
<tr>
<th>IRB#</th>
<th>Trial Name</th>
<th>Criteria</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB#21349</td>
<td>MORAB-202 (Phase 1)</td>
<td>• <strong>TNBC</strong>: Previously treated (cytotoxic or targeted anticancer agents) in the metastatic setting.</td>
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</tr>
<tr>
<td>IRB#21766</td>
<td>GEN001 (Phase 1)</td>
<td>• Patients must have progressed on at least two lines of approved therapy for their histological subtype</td>
<td>1</td>
</tr>
<tr>
<td>IRB#21508</td>
<td>ORIC-101 (Phase 1)</td>
<td>• <strong>TNBC</strong> with no alternative effective standard therapy</td>
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</tr>
<tr>
<td>IRB#21548</td>
<td>AMG 650 (Phase 1)</td>
<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>1B</td>
</tr>
<tr>
<td>IRB#21819</td>
<td>ASTX029 (Phase 1)</td>
<td>• <strong>Phase 1B</strong>: documented activating gene mutations in <strong>BRAF</strong> (BRAF V600 mutation or activating atypical non-V600 aberrations), <strong>KRAS</strong>, <strong>NRAS</strong>, or <strong>HRAS</strong></td>
<td>1B</td>
</tr>
</tbody>
</table>

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

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