NEOADJUVANT THERAPY

HR-positive
HER2-negative

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

- IRB# 21243
  - Neoadjuvant Abemaciclib and Niraparib (PANNTHR)

- 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

IRB# 22388
- Ip/Nivo/CRO: Peri-Operative Ipilimumab+Nivolumab and Cryoablation vs. Standard Care

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

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

25 May 2021
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 Ipiilimumab+Nivolumab and Cryoablation Versus Standard Care

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

25 May 2021
BREAST CANCER

METASTATIC THERAPY

HER2-positive

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

Key

- Open for Enrollment
- In Development
- Enrollment on Hold

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

25 May 2021
BREAST CANCER

METASTATIC THERAPY

Triple Negative

1L
IRB#18504
AMTEC: Olaparib + Durvalumab

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

2L
IRB#18504
AMTEC: Olaparib + Durvalumab
IRB 22765 DESTINY-Breast08: Phase 1b Study of T-DXd Combinations in HER2-low a/mBC

>2L
IRB#18504
AMTEC: Olaparib + Durvalumab
IRB 22765 DESTINY-Breast08: Phase 1b Study of T-DXd Combinations in HER2-low a/mBC

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

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

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

**Continued**

<table>
<thead>
<tr>
<th>IRB#</th>
<th>Trial Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>21349</td>
<td><strong>MORAB-202 (Phase 1)</strong>&lt;br&gt;• TNBC: Previously treated (cytotoxic or targeted anticancer agents) in the metastatic setting.</td>
</tr>
<tr>
<td>21766</td>
<td><strong>GEN001 (Phase 1)</strong>&lt;br&gt;• Patients must have progressed on at least two lines of approved therapy for their histological subtype</td>
</tr>
<tr>
<td>21508</td>
<td><strong>ORIC-101 (Phase 1)</strong>&lt;br&gt;• TNBC with no alternative effective standard therapy</td>
</tr>
<tr>
<td>21548</td>
<td><strong>AMG 650 (Phase 1)</strong>&lt;br&gt;• TNBC relapsed/refractory to at least one line of systemic chemotherapy in the metastatic setting or intolerant of existing therapy(ies).</td>
</tr>
<tr>
<td>21819</td>
<td><strong>ASTX029 (Phase 1)</strong>&lt;br&gt;• <strong>Phase 1B</strong>: documented activating gene mutations in BRAF (BRAF V600 mutation or activating atypical non-V600 aberrations), KRAS, NRAS, or HRAS</td>
</tr>
</tbody>
</table>

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

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25 May 2021