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
Ipi/Nivo/CROT: Peri-Operative Ipilimumab + Nivolumab and Cryoablation

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

IRB#22791
eMonarcHER: Abemaciclib/Placebo + Standard Adjuvant Endocrine Therapy

Triple Negative

IRB#22388
Ipi/Nivo/Cryo: Peri-Operative Ipilimumab+Nivolumab and Cryoablation

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

Key
- Open for Enrollment
- In Development
- Enrollment on Hold
BREAST CANCER

METASTATIC THERAPY

ENDOCRINE

HR-positive
HER2-negative

Physician's Choice

CHÉMO

No trial currently available

1L

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

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

IRB20440
CT7001-001: CT7001 Alone and in Combination with Anti-Cancer Treatments

IRB 22765 DESTINY-Breast08: Phase 1b Study of T-DXd Combinations in HER2-low a/mBC

IRB21441
EA1183: FDG-PET/CT

2L

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

IRB 22765 DESTINY-Breast08: Phase 1b Study of T-DXd Combinations in HER2-low a/mBC

IRB21441
EA1183: FDG-PET/CT

>2L

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

IRB 22765 DESTINY-Breast08: Phase 1b Study of T-DXd Combinations in HER2-low a/mBC

IRB21441
EA1183: FDG-PET/CT

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

METASTATIC THERAPY

HER2-positive

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

2L
- IRB#20112
  HER2CLIMB-02: T-DM1 and Tucatinib/Placebo
- IRB#19830
  TDM1 +/- Palbociclib
- IRB#21441
  EA1183: FDG-PET/CT

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

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

METASTATIC THERAPY

1L
- IRB#18504
  - AMTEC: Olaparib + Durvalumab

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

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

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
## CROSS-DISEASE TRIALS

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Description</th>
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<tbody>
<tr>
<td>IRB#15588</td>
<td>Heavily Pre-treated&lt;br&gt;HR+HER2-; HER2+; TNBC</td>
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<tr>
<td>IRB#20679</td>
<td>HR+HER2-; HER2+; TNBC&lt;br&gt;Pre-screen (molecular target)</td>
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<tr>
<td>IRB#19904</td>
<td>Heavily Pre-treated&lt;br&gt;Pre-screen required</td>
</tr>
<tr>
<td>IRB#19992</td>
<td>Pre-screen (molecular target)</td>
</tr>
<tr>
<td>IRB#18084</td>
<td>Pre-screen (rare molecular target)</td>
</tr>
<tr>
<td>IRB#19489</td>
<td>Targeting Metastatic Breast Cancer and Breast Cancer Stem Cells with Lutathera</td>
</tr>
<tr>
<td>IRB#16676</td>
<td>Advanced solid tumor with oncogenic RET fusion (expected to close soon)</td>
</tr>
<tr>
<td>IRB#18164</td>
<td>RET fusion-positive</td>
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</tbody>
</table>

[http://www.ohsu.edu/research/rda/so/knight.php](http://www.ohsu.edu/research/rda/so/knight.php)
<table>
<thead>
<tr>
<th>IRB#</th>
<th>Trial Details</th>
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<tbody>
<tr>
<td>21349</td>
<td>MORAB-202 (Phase 1)</td>
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<tr>
<td>21766</td>
<td>GEN001 (Phase 1)</td>
</tr>
<tr>
<td>21508</td>
<td>ORIC-101 (Phase 1)</td>
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<td>21548</td>
<td>AMG 650 (Phase 1)</td>
</tr>
<tr>
<td>21819</td>
<td>ASTX029 (Phase 1)</td>
</tr>
</tbody>
</table>

- **TNBC**: Previously treated (cytotoxic or targeted anticancer agents) in the metastatic setting.
- Patients must have progressed on at least two lines of approved therapy for their histological subtype.
- **TNBC** with no alternative effective standard therapy.
- **TNBC** relapsed/refractory to at least one line of systemic chemotherapy in the metastatic setting or intolerant of existing therapy(ies).
- **Phase 1B**: Documented activating gene mutations in BRAF (BRAF V600 mutation or activating atypical non-V600 aberrations), KRAS, NRAS, or HRAS.

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