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

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

[Link to OHSU website for research information](http://www.ohsu.edu/research/rda/so/knight.php)
HR-positive
HER2-negative

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

HER2-positive

No trials currently available

Triple Negative

No trials currently available

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

**1L**
- **IRB#22225**
  - **SERENA-4**: AZD9833 with palbociclib vs. anastrozole with palbociclib

**2L**
- **IRB#22225**
  - OP-1250-001: A Dose Escalation/Expansion study of OP-1250
- **IRB#22730**
  - DESTINY: Phase 1b Study of T-DXd Combinations in HER2-low a/mBC

**>2L**
- **IRB#22225**
  - OP-1250-001: A Dose Escalation/Expansion study of OP-1250
- **IRB#22730**
  - DESTINY: Phase 1b Study of T-DXd Combinations in HER2-low a/mBC

**HR-positive HER2-negative**
- **Physician’s Choice**
- **CHEMO**
  - **IRB 22765 DESTINY Breast08**: Phase 1b Study of T-DXd Combinations in HER2-low a/mBC

**In Development**
- **IRB 23524 TROPION Breast01**: DATO-DXd vs. Chemo
- **IRB 23794 Keynote Breast08**: Pembrolizumab/Placebo Plus Chemotherapy

**Enrollment on Hold**
- **IRB#21441**
  - EA1183: FDG-PET/CT

[http://www.ohsu.edu/research/rda/sc/knight.php](http://www.ohsu.edu/research/rda/sc/knight.php)
BREAST CANCER

METASTATIC THERAPY

HER2-positive

1L
IRB#21441
EA1183: FDG-PET/CT

IRB#19078
S1501: Carvediol in Preventing Cardiac Toxicity

2L
IRB#21441
EA1183: FDG-PET/CT

IRB#19078
S1501: Carvediol in Preventing Cardiac Toxicity

>2L
IRB#19078
S1501: Carvediol in Preventing Cardiac Toxicity

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

04 May 2022
<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Description</th>
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<tbody>
<tr>
<td>IRB#15588</td>
<td>Heavily Pre-treated, HR+HER2-, HER2+, TNBC (SMMART-PRIME)</td>
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<tr>
<td>IRB#20679</td>
<td>HR+HER2-, HER2+, TNBC, Pre-screen (molecular target) (SMMART-ACT)</td>
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<tr>
<td>IRB#19904</td>
<td>Heavily Pre-treated, Pre-screen required (NEO-RAY (Nuc Med))</td>
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<td>IRB#19992</td>
<td>Pre-screen (molecular target) (EAY131 (MATCH))</td>
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<tr>
<td>IRB#18084</td>
<td>Pre-screen (rare molecular target) (S1609 (DART))</td>
</tr>
<tr>
<td>IRB#19489</td>
<td>Targeting Metastatic Breast Cancer and Breast Cancer Stem Cells with Lutathera (Lutathera IIT)</td>
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<tr>
<td>IRB#16676</td>
<td>Advanced solid tumor with oncogenic RET fusion (expected to close soon) (BLU-667 (Phase 1))</td>
</tr>
<tr>
<td>IRB#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)
BREAST CANCER

To inquire about Phase 1 trial open slots please contact Phase1@ohsu.edu.

- **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

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

04 May 2022
• A Phase 1, First in Human Study of Adenovirally Transduced Autologous Macrophages Engineered to Contain an Anti-HER2 Chimeric Antigen Receptor in Subjects with HER2 Overexpressing Solid Tumors. Principal Investigator: Richard Maziarz, MD

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