BREAST CANCER

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

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

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

Triple Negative

No trials currently available

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

METASTATIC THERAPY

ENDOCRINE

HR-positive
HER2-negative

CHEMO

Physician's Choice

1L

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

2L

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

IRB#22756 Keynote-B49: Pembrolizumab/Placebo Plus Chemotherapy

IRB#22730
AZD9833 with palbociclib

IRB#21441
EA1183: FDG-PET/CT

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

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

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

IRB#23524
TROPION-Breast01: DATO-DXd vs. Chemo

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

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IRB 23524
TROPION-Breast01: DATO-DXd vs. Chemo

IRB 23524
TROPION-Breast01: DATO-DXd vs. Chemo

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

10 Sep 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

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

Key

[Diagram showing enrollment statuses: Open for Enrollment, In Development, Enrollment on Hold]
BREAST CANCER

METASTATIC THERAPY

**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

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

[Diagram showing the flow of therapy options for metastatic breast cancer](http://www.ohsu.edu/research/rda/so/knight.php)

**Key**
- Open for Enrollment
- In Development
- Enrollment on Hold
### CROSS-DISEASE TRIALS

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

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### CROSS-DISEASE TRIALS

#### Continued

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<th>IRB#</th>
<th>Trial Details</th>
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<td>MORAB-202 (Phase 1)</td>
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<td>GEN001 (Phase 1)</td>
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<td>21508</td>
<td>ORIC-101 (Phase 1)</td>
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<td>21548</td>
<td>AMG 650 (Phase 1)</td>
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<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.

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

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

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10 Sep 2021