Sample Cancer Type: Breast Cancer

<table>
<thead>
<tr>
<th>Gene Variant</th>
<th>In this cancer type</th>
<th>In other cancer type</th>
<th>Contraindicated</th>
<th>Both for use and contraindicated</th>
<th>No evidence Global Clinical Trials</th>
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<tbody>
<tr>
<td>FGFR4 amplification</td>
<td>![x]</td>
<td>![x]</td>
<td>![x]</td>
<td>![x]</td>
<td>![7]</td>
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</tbody>
</table>

**Comment:**
The DNA and RNA extracted from this sample were of optimal quality. The Oncofocus assay on which the sample was run met all assay specific quality metrics.

175 genes were targeted covering 2470 unique coding hot spots, 281 fusions and 19 CNV genes for actionable mutations linked to 484 anti-cancer targeted therapies.

The following actionable mutations were detected

**Variant Summary**
### ERBB2 amplification

<table>
<thead>
<tr>
<th>Relevant Therapy</th>
<th>EMA</th>
<th>US-FDA</th>
<th>ESMO</th>
<th>US-NCCN</th>
<th>Global Clinical Trials*</th>
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</thead>
<tbody>
<tr>
<td>trastuzumab</td>
<td>🌟</td>
<td>🌟</td>
<td>✗</td>
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<td>(IV)</td>
</tr>
<tr>
<td>trastuzumab + capecitabine</td>
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<td>✗</td>
<td>✗</td>
<td>🌟</td>
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<tr>
<td>trastuzumab + docetaxel</td>
<td>🌟</td>
<td>✗</td>
<td>✗</td>
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<td>trastuzumab + paclitaxel</td>
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<td>✗</td>
<td>✗</td>
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<tr>
<td>trastuzumab + aromatase inhibitor</td>
<td>🌟</td>
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<td>✗</td>
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</tr>
<tr>
<td>trastuzumab + carboplatin + docetaxel</td>
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<td>✗</td>
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<td>trastuzumab + cisplatin + fluorouracil</td>
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<td>🌟</td>
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<td>(IV)</td>
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<tr>
<td>pertuzumab + trastuzumab + docetaxel</td>
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<td>🌟</td>
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<tr>
<td>lapatinib + trastuzumab</td>
<td>🌟</td>
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<td>🌟</td>
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<td>(II)</td>
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<tr>
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</tbody>
</table>

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**ONC16-: 0155**

www.oncologica.com

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

**DISCLAIMER:** The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2016.09(002).
## ERBB2 amplification (continued)

<table>
<thead>
<tr>
<th>Relevant Therapy</th>
<th>EMA</th>
<th>US-FDA</th>
<th>ESMO</th>
<th>US-NCCN</th>
<th>Global Clinical Trials*</th>
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<tbody>
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<td>(III)</td>
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<td>(III)</td>
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<td>✗</td>
<td>(II)</td>
</tr>
</tbody>
</table>

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.
### Relevant Therapy Summary (continued)

<table>
<thead>
<tr>
<th>Relevant Therapy</th>
<th>EMA</th>
<th>US-FDA</th>
<th>ESMO</th>
<th>US-NCCN</th>
<th>Global Clinical Trials*</th>
</tr>
</thead>
<tbody>
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<tr>
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<td>×</td>
<td>⬤ (II)</td>
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<td>×</td>
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<tr>
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<td>×</td>
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<td>⬤ (II)</td>
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<tr>
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<td>×</td>
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</tr>
<tr>
<td>everolimus + trastuzumab + chemotherapy</td>
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<tr>
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</tbody>
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### Relevant Therapy Summary (continued)

#### ERBB2 amplification (continued)

<table>
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<tr>
<th>Relevant Therapy</th>
<th>EMA</th>
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<th>ESMO</th>
<th>US-NCCN</th>
<th>Global Clinical Trials*</th>
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<tr>
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</tbody>
</table>

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### Relevant Therapy Summary (continued)

![In this cancer type](image)
![In other cancer type](image)
![In this cancer type and other cancer types](image)
![Contraindicated](image)
![Both for use and contraindicated](image)
![No evidence](image)

### ERBB2 amplification (continued)

<table>
<thead>
<tr>
<th>Relevant Therapy</th>
<th>EMA</th>
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</tr>
</thead>
<tbody>
<tr>
<td>trastuzumab + letrozole</td>
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<td>(II)</td>
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<tr>
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<tr>
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<td>(I/II)</td>
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<td>(I/II)</td>
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<td>(I)</td>
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* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.

**ONC16- 0155**

**www.oncologica.com**

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### Relevant Therapy Summary (continued)

#### ERBB2 amplification (continued)

<table>
<thead>
<tr>
<th>Relevant Therapy</th>
<th>EMA</th>
<th>US-FDA</th>
<th>ESMO</th>
<th>US-NCCN</th>
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#### FGFR4 amplification

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<tr>
<th>Relevant Therapy</th>
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<th>ESMO</th>
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Relevant Therapy Summary (continued)

<table>
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<th>Relevant Therapy</th>
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Current EMA Information

- In this cancer type
- In other cancer type
- In this cancer type and other cancer types
- Contraindicated

EMA information is current as of 2016-07-01. For the most up-to-date information, search www.ema.europa.eu/ema.

ERBB2 amplification

- **trastuzumab, trastuzumab + aromatase inhibitor, trastuzumab + capecitabine, trastuzumab + carboplatin + docetaxel, trastuzumab + cisplatin + fluorouracil, trastuzumab + docetaxel, trastuzumab + paclitaxel**
  - **Cancer type:** Breast Cancer, Esophageal Cancer, Gastric Cancer
  - **Label as of:** 2016-05-19
  - **Variant class:** ERBB2 amplification

- **ado-trastuzumab emtansine**
  - **Cancer type:** Breast Cancer
  - **Label as of:** 2016-05-19
  - **Variant class:** ERBB2 amplification

- **lapatinib + aromatase inhibitor, lapatinib + capecitabine, lapatinib + trastuzumab**
  - **Cancer type:** Breast Cancer
  - **Label as of:** 2015-08-11
  - **Variant class:** ERBB2 amplification

- **pertuzumab + trastuzumab + docetaxel**
  - **Cancer type:** Breast Cancer
  - **Label as of:** 2016-05-19
  - **Variant class:** ERBB2 amplification

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Current US-FDA Information

In this cancer type  ☑  In other cancer type  ☐  In this cancer type and other cancer types  ☑  Contraindicated

US-FDA information is current as of 2016-07-01. For the most up-to-date information, search www.fda.gov.

### ERBB2 amplification

#### trastuzumab

- **Cancer type:** Breast Cancer, Esophageal Cancer, Gastric Cancer
- **Label as of:** 2015-03-17
- **Variant class:** ERBB2 amplification

**Indications and usage:**

Herceptin is a HER2/neu receptor antagonist indicated for:
- the treatment of HER2 overexpressing breast cancer.
- the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

**Reference:**

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/103792s5330lbl.pdf

#### ado-trastuzumab emtansine

- **Cancer type:** Breast Cancer
- **Label as of:** 2016-04-28
- **Variant class:** ERBB2 amplification

**Indications and usage:**

KADCYLA® is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:
- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy.

**Reference:**

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125427s094lbl.pdf

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pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer  Label as of: 2016-03-22  Variant class: ERBB2 amplification

Indications and usage:

PERJETA® is a HER2/neu receptor antagonist indicated for:

- Use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
- Use in combination with trastuzumab and docetaxel as neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival.

Limitations of Use:

- The safety of PERJETA® as part of a doxorubicin-containing regimen has not been established.
- The safety of PERJETA® administered for greater than 6 cycles for early breast cancer has not been established.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125409s109lbl.pdf
**Current ESMO Information**

- In this cancer type
- In other cancer type
- In this cancer type and other cancer types
- Contraindicated

ESMO information is current as of 2016-06-07. For the most up-to-date information, search www.esmo.org.

### ERBB2 amplification

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Cancer type: Breast Cancer</th>
<th>Variant class: ERBB2 amplification</th>
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</thead>
<tbody>
<tr>
<td><strong>trastuzumab + chemotherapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>trastuzumab + hormone therapy + chemotherapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>trastuzumab + chemotherapy</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Other criteria:** ER negative

**ESMO Recommendation category:** IV, B

**Population segment (Line of therapy):** Not specified


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ERBB2 amplification (continued)

ado-trastuzumab emtansine

Cancer type: Breast Cancer  
Variant class: ERBB2 positive

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Progression after trastuzumab based therapy (Second-line therapy)


pertuzumab + trastuzumab + chemotherapy

Cancer type: Breast Cancer  
Variant class: ERBB2 positive

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Previously untreated metastatic breast cancer (First-line therapy)


trastuzumab + chemotherapy

Cancer type: Breast Cancer  
Variant class: ERBB2 positive

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Metastatic breast cancer previously treated in the adjuvant setting (First-line therapy)
- Metastatic breast cancer untreated with trastuzumab (First-line therapy)


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ERBB2 amplification (continued)

- lapatinib + trastuzumab
  
  **Cancer type:** Breast Cancer  
  **Variant class:** ERBB2 positive  
  **ESMO Recommendation category:** I, B  
  
  **Population segment (Line of therapy):**  
  - Progression on trastuzumab (Not specified)  
  

- pertuzumab
  
  **Cancer type:** Breast Cancer  
  **Variant class:** ERBB2 positive  
  **ESMO Recommendation category:** II, C  
  
  **Population segment (Line of therapy):**  
  - Metastatic breast cancer previously untreated with pertuzumab (After first-line therapy)  
  
Current US-NCCN Information

In this cancer type  In other cancer type  In this cancer type and other cancer types  Contraindicated

US-NCCN information is current as of 2016-06-07. For the most up-to-date information, search www.nccn.org. For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

---

**ERBB2 amplification**

1. **pertuzumab + trastuzumab + docetaxel**
   - **Cancer type:** Breast Cancer
   - **Variant class:** ERBB2 amplification
   - **US-NCCN Recommendation category:** 1
   - **Population segment (Line of therapy):**
     - Metastatic breast cancer (First-line therapy)

2. **trastuzumab + chemotherapy**
   - **Cancer type:** Breast Cancer
   - **Variant class:** ERBB2 amplification
   - **Other criteria:** ER negative and/or PR negative
   - **US-NCCN Recommendation category:** 1
   - **Population segment (Line of therapy):**
     - Tumors >1cm (Not specified)
     - One or more > 2mm ipsilateral axillary lymph node metastases (Not specified)

3. **trastuzumab + hormone therapy + chemotherapy**
   - **Cancer type:** Breast Cancer
   - **Variant class:** ERBB2 amplification
   - **Other criteria:** ER positive and/or PR positive
   - **US-NCCN Recommendation category:** 1
   - **Population segment (Line of therapy):**
     - Node positive, Ductal, Lobular, Mixed, Metaplastic tumors greater than 1 mm to one or more ipsilateral axillary lymph node metastases (Not specified)

---

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ERBB2 amplification (continued)

ado-trastuzumab emtansine

- Cancer type: Breast Cancer
- Variant class: ERBB2 amplification
- US-NCCN Recommendation category: 2A
- Population segment (Line of therapy):
  - Metastatic breast cancer previously treated with trastuzumab-based regimen (Not specified)

hormone therapy

- Cancer type: Breast Cancer
- Variant class: ERBB2 amplification
- Other criteria: ER positive and/or PR positive
- US-NCCN Recommendation category: 2A
- Population segment (Line of therapy):
  - Ductal, Lobular, Mixed, Metaplastic tumors less than or equal to 0.5cm (pT1, PT2, pT3 and pN0) (Not specified)

lapatinib + capecitabine

- Cancer type: Breast Cancer
- Variant class: ERBB2 amplification
- US-NCCN Recommendation category: 2A
- Population segment (Line of therapy):
  - Metastatic breast cancer previously treated with trastuzumab-based regimen (Not specified)

lapatinib + trastuzumab

- Cancer type: Breast Cancer
- Variant class: ERBB2 amplification
- US-NCCN Recommendation category: 2A
- Population segment (Line of therapy):
  - Metastatic breast cancer previously treated with trastuzumab-based regimen (Not specified)

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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**ERBB2 amplification (continued)**

### pertuzumab + trastuzumab + chemotherapy

- **Cancer type:** Breast Cancer  
  **Variant class:** ERBB2 amplification  
- **Other criteria:** ER negative and PR negative, ER positive and/or PR positive  
- **US-NCCN Recommendation category:** 2A  
- **Population segment (Line of therapy):**  
  - Did not receive pertuzumab as part of neoadjuvant therapy (Neoadjuvant/adjuvant therapy)  
  - Disease progression after treatment with trastuzumab-based therapy without pertuzumab (Not specified)

**Reference:** NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

### pertuzumab + trastuzumab + paclitaxel

- **Cancer type:** Breast Cancer  
  **Variant class:** ERBB2 amplification  
- **US-NCCN Recommendation category:** 2A  
- **Population segment (Line of therapy):**  
  - Metastatic breast cancer (First-line therapy)

**Reference:** NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

### trastuzumab + capecitabine

- **Cancer type:** Breast Cancer  
  **Variant class:** ERBB2 amplification  
- **US-NCCN Recommendation category:** 2A  
- **Population segment (Line of therapy):**  
  - Metastatic breast cancer (First-line therapy)  
  - Metastatic breast cancer previously treated with trastuzumab-based regimen (Not specified)

**Reference:** NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]
ERBB2 amplification (continued)

- trastuzumab + carboplatin + paclitaxel
  
  **Cancer type:** Breast Cancer  
  **Variant class:** ERBB2 amplification  
  **US-NCCN Recommendation category:** 2A  
  
  **Population segment (Line of therapy):**  
  - Metastatic breast cancer (First-line therapy)  
  
  **Reference:** NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

- trastuzumab + chemotherapy
  
  **Cancer type:** Breast Cancer  
  **Variant class:** ERBB2 amplification  
  **Other criteria:** ER positive and/or PR positive  
  **US-NCCN Recommendation category:** 2A  
  
  **Population segment (Line of therapy):**  
  - Ductal, Lobular, Mixed, Metaplastic tumors less than or equal to 0.5cm (pT1, PT2, pT3 and pN1mi) (Not specified)  
  - Recurrent or stage IV, Endocrine refractory (Not specified)  
  
  **Reference:** NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

- trastuzumab + chemotherapy
  
  **Cancer type:** Breast Cancer  
  **Variant class:** ERBB2 amplification  
  **Other criteria:** ER negative and/or PR negative  
  **US-NCCN Recommendation category:** 2A  
  
  **Population segment (Line of therapy):**  
  - Recurrent or stage IV, Endocrine refractory (Not specified)  
  
  **Reference:** NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]
## ERBB2 amplification (continued)

### trastuzumab + docetaxel

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<th>Variant class</th>
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<th>Population segment (Line of therapy)</th>
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</table>

### trastuzumab + hormone therapy

<table>
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<th>Cancer type</th>
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### trastuzumab + hormone therapy + chemotherapy

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<th>Variant class</th>
<th>US-NCCN Recommendation category</th>
<th>Population segment (Line of therapy)</th>
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<td>NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]</td>
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</table>
ERBB2 amplification (continued)

- **trastuzumab + paclitaxel**
  
  Cancer type: Breast Cancer  
  Variant class: ERBB2 amplification  
  US-NCCN Recommendation category: 2A  
  
  Population segment (Line of therapy):  
  - Low-risk stage I disease (Neoadjuvant/adjuvant therapy)  
  - Metastatic breast cancer (First-line therapy)  
  

- **trastuzumab + vinorelbine**
  
  Cancer type: Breast Cancer  
  Variant class: ERBB2 amplification  
  US-NCCN Recommendation category: 2A  
  
  Population segment (Line of therapy):  
  - Metastatic breast cancer (First-line therapy)  
  

- **trastuzumab + hormone therapy**
  
  Cancer type: Breast Cancer  
  Variant class: ERBB2 amplification  
  
  Other criteria: ER positive and/or PR positive  
  US-NCCN Recommendation category: 2B  
  
  Population segment (Line of therapy):  
  - Ductal, Lobular, Mixed, Metaplastic tumors less than or equal to 0.5cm (pT1, pT2, pT3 and pN0) (Not specified)  
  
ERBB2 amplification (continued)

- **trastuzumab + hormone therapy + chemotherapy**
  - **Cancer type:** Breast Cancer
  - **Variant class:** ERBB2 amplification
  - **Other criteria:** ER positive and/or PR positive
  - **US-NCCN Recommendation category:** 2B
  - **Population segment (Line of therapy):**
    - Ductal, Lobular, Mixed, Metaplastic tumors less than or equal to 0.5cm (pT1, PT2, pT3 and pN0) (Not specified)

- **trastuzumab + cisplatin + fluoropyrimidine**
  - **Cancer type:** Esophageal Cancer
  - **Variant class:** ERBB2 amplification
  - **US-NCCN Recommendation category:** 1
  - **Population segment (Line of therapy):**
    - Locally advanced or metastatic adenocarcinoma (First-line therapy)

- **trastuzumab + cisplatin + fluoropyrimidine**
  - **Cancer type:** Gastric Cancer
  - **Variant class:** ERBB2 amplification
  - **US-NCCN Recommendation category:** 1
  - **Population segment (Line of therapy):**
    - Locally advanced or metastatic gastric cancer (First-line therapy)
  - **Reference:** NCCN Guidelines® - NCCN-Gastric Cancer [Version 1.2016]

- **trastuzumab + chemotherapy (other)**
  - **Cancer type:** Esophageal Cancer
  - **Variant class:** ERBB2 amplification
  - **US-NCCN Recommendation category:** 2B
  - **Population segment (Line of therapy):**
    - Locally advanced or metastatic adenocarcinoma (First-line therapy)

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ERBB2 amplification (continued)

- **trastuzumab + chemotherapy (other)**

  - **Cancer type:** Gastric Cancer
  - **Variant class:** ERBB2 amplification
  - **US-NCCN Recommendation category:** 2B
  - **Population segment (Line of therapy):**
    - Locally advanced or metastatic gastric cancer (First-line therapy)
  - **Reference:** NCCN Guidelines® - NCCN-Gastric Cancer [Version 1.2016]
Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-06-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

**ERBB2 amplification**

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<thead>
<tr>
<th>Title</th>
<th>Cancer type</th>
<th>Variant class</th>
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<th>Population segments</th>
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<tr>
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<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>TrialTroveID-196620, UMIN000012210</td>
<td>HER2 positive, Line of therapy N/A, Stage IV</td>
<td>IV</td>
<td>pertuzumab + chemotherapy</td>
<td>Japan</td>
</tr>
<tr>
<td>No NCT ID - see other identifier(s)</td>
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</tr>
<tr>
<td>A Post-Marketing Clinical Study to Evaluate the Efficacy and Safety of Pertuzumab Combined with Trastuzumab and Docetaxel as First Line Treatment in HER2-Positive Inoperable or Recurrent Breast Cancer</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>COMACHI, JapicCTI-132321, TrialTroveID-197276</td>
<td>First line, HER2 positive, Stage III, Stage IV</td>
<td>IV</td>
<td>pertuzumab + trastuzumab + chemotherapy</td>
<td>Japan</td>
</tr>
<tr>
<td>No NCT ID - see other identifier(s)</td>
<td></td>
<td></td>
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<tr>
<td>Observational Study of Pertuzumab in Combination with Trastuzumab and Docetaxel in Patients with Metastatic HER2-Positive Breast Cancer that have the History of Trastuzumab Treatment</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>TrialTroveID-198130, UMIN000012444</td>
<td>HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
<td>IV</td>
<td>pertuzumab + trastuzumab + chemotherapy</td>
<td>Japan</td>
</tr>
</tbody>
</table>

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ERBB2 amplification (continued)

NCT02419742
An Indian Multicentric Open Label Prospective Phase IV Study to Evaluate Safety & Efficacy of Trastuzumab in HER2 Positive, and High Risk Node Negative Breast Cancer as Part of a Treatment Regimen Consisting of Doxorubicin, Cyclophosphamide, With Either Docetaxel or Paclitaxel (ACTH) or Docetaxel and Carboplatin (TCH)
Cancer type: Breast Cancer
Variant class: ERBB2 amplification

Other identifiers: CR1/2015/05/005789, ML28714, TrialTroveID-255808
Population segments: HER2 positive, Line of therapy N/A, Stage I, Stage II, Stage III
Phase: IV
Therapy: trastuzumab + chemotherapy
Country: India

NCT02305641
Post-marketing surveillance of kadcyla in breast cancer
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: ML29629, TrialTroveID-222026
Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: IV
Therapy: ado-trastuzumab emtansine
Country: Republic of Korea

No NCT ID - see other identifier(s)
The effect of trastuzumab emtansine (T-DM1) to the platelets for HER2-positive advanced breast cancer patients
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: TrialTroveID-215196, UMIN000014750
Population segments: HER2 positive, Line of therapy N/A, Stage III, Stage IV
Phase: IV
Therapies: ado-trastuzumab emtansine, trastuzumab
Country: Japan

No NCT ID - see other identifier(s)
Observational study of Pertuzumab,Trastuzumab and taxane combination therapy for patient with pretreated HER2-positive advanced or recurrent breast cancer.
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: TrialTroveID-206144, UMIN000013607
Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: IV
Therapy: pertuzumab + trastuzumab + chemotherapy
Country: Japan
## ERBB2 amplification (continued)

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Description</th>
<th>Other identifiers</th>
<th>Population segments</th>
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<th>Therapy</th>
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<tr>
<td>NCT01777958</td>
<td>Noninterventional Study - Advanced HER2-positive Breast Cancer (Metastatic or Locally Recurrent, Inoperable): First-Line Treatment With PERJETA After Adjuvant Herceptin Therapy (HELENA)</td>
<td>HELENA, ML28750, ML28750 HELENA, NIS HELENA ML28750, TrialTroveID-180579</td>
<td>First line, HER2 positive, Stage III, Stage IV</td>
<td>IV</td>
<td>pertuzumab + trastuzumab + chemotherapy</td>
<td>Germany</td>
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<tr>
<td>NCT02445586</td>
<td>A Phase IV, Multicenter, Open-Label, Single Arm Study of Pertuzumab (In Combination With Trastuzumab and Docetaxel) In First Line Treatment of Indian Patients With HER2- Positive Advanced (Metastatic or Locally Recurrent) Breast Cancer</td>
<td>CTRI/2015/05/005766, ML29282, TrialTroveID-257501</td>
<td>First line, HER2 positive, Stage III, Stage IV</td>
<td>IV</td>
<td>pertuzumab + trastuzumab + chemotherapy</td>
<td>India</td>
</tr>
<tr>
<td>No NCT ID - see other identifier(s)</td>
<td>Trastuzumab-Induced Early Cardiac Dysfunction Assessed by Speckle Tracking Echocardiography: Correlation with Chronic Inflammation and Oxidative Stress Markers</td>
<td>TrialTroveID-175802</td>
<td>(N/A), HER2 positive, Line of therapy N/A</td>
<td>IV</td>
<td>trastuzumab</td>
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</table>

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 positive
### NCT01808573
A Study of Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in Patients With HER2+ Metastatic Breast Cancer Who Have Received Two or More Prior HER2 Directed Regimens in the Metastatic Setting

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** 041304, 13-521, 13470, 1378GCC, 14-PPD-4, AAAM2506, AMC 2013-0450, CTMS# 15-2058, EudraCT Number: 2012-004492-38, NALA, NCI-2013-01418, NCRNS26, NCRNS26 NALA, PUMA NALA, PUMA-NER-1301, REec-2014-0746, TrialTroveID-182199, UKCRN ID: 14707

**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

**Phase:** III

**Therapies:** lapatinib + chemotherapy, neratinib + chemotherapy

**Countries:** Argentina, Australia, Austria, Belgium, Brazil, Canada, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, Ireland, Israel, Italy, Japan, Republic of Korea, Russian Federation, Singapore, Spain, Sweden, Switzerland, Taiwan, United Kingdom, United States

**US States:** AZ, CA, CO, DC, FL, GA, HI, IL, IN, KY, MA, MD, MO, MS, NC, NE, NJ, NY, OH, PA, RI, TN, TX, VT, WV

**US Contact:** Puma Biotechnology Clinical Operations [424-248-6500; clinicaltrials@pumabiotechnology.com]

### NCT01104571
Effect of Perioperative AntiHER-2 Therapy on Early Breast Cancer Study - Biological Phase (EPHOS-B)

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification


**Population segments:** Adjuvant, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III

**Other inclusion criteria:** ER positive/negative

**Phase:** III

**Therapies:** lapatinib, lapatinib + trastuzumab, trastuzumab

**Country:** United Kingdom
### ERBB2 amplification (continued)

#### NCT02492711
A Phase 3, Randomized Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients With HER2+ Metastatic Breast Cancer Who Have Received Prior Anti-HER2 Therapies and Require Systemic Treatment  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** 157515, CP-MGAH22-04, EudraCT Number: 2015-000380-13, NCI-2016-00295, REec-2015-1816, SOPHIA, TrialTroveID-222276  
**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV  
**Other inclusion criteria:** ER positive/negative, PR positive/negative  
**Phase:** III  
**Therapies:** margetuximab + chemotherapy, trastuzumab + chemotherapy  
**Countries:** Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Italy, Netherlands, Portugal, Spain, United Kingdom, United States  
**US States:** AL, AZ, CA, CO, DC, FL, GA, HI, IA, IL, IN, KY, MA, MD, ME, MO, NH, NJ, NY, OH, OK, PA, TN, TX, UT, VA, WA  
**US Contact:** Seila Liv [650-624-2662; livs@macrogenics.com]

#### NCT02344472
DETECT V / CHEVENDO CHemo- Versus ENDoocrine Therapy in Combination With Dual HER2-targeted Therapy of Herceptin (Trastuzumab) and Perjeta (Pertuzumab) in Patients With HER2 Positive and Hormone-receptor Positive Metastatic Breast Cancer  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** CHEVENDO, D-V, Detect V, DV, EudraCT Number: 2014-002249-22, TrialTroveID-251026  
**Population segments:** First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV  
**Other inclusion criteria:** ER positive, PR positive  
**Phase:** III  
**Therapies:** pertuzumab + trastuzumab + anastrozole, pertuzumab + trastuzumab + chemotherapy, pertuzumab + trastuzumab + exemestane, pertuzumab + trastuzumab + fulvestrant, pertuzumab + trastuzumab + letrozole, pertuzumab + trastuzumab + tamoxifen  
**Country:** Germany
NCT02402712
A Multicenter, Open-Label, Single-Arm Safety Study Of Herceptin SC In Combination With Perjeta And Docetaxel In Treatment Of Patients With HER2-Positive Advanced Breast Cancer (Metastatic Or Locally Recurrent)
Cancer type: Breast Cancer
Variant class: ERBB2 amplification
Other identifiers: BO29159, CTBE2015000297, EudraCT Number: 2014-001458-40, MetaPHer, REec-2015-1454, TrialTroveID-253317, UKCRN ID: 18662
Population segments: First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage II, Stage III, Stage IV
Phase: III
Therapy: pertuzumab + trastuzumab + chemotherapy
Countries: Belgium, Bulgaria, Canada, France, Germany, Hungary, Italy, Poland, Portugal, Spain, United Kingdom

NCT02125344
A Randomized Phase III Trial Comparing Two Dose-dense, Dose-intensified Approaches (ETC and PM(Cb)) for Neoadjuvant Treatment of Patients With High-risk Early Breast Cancer (GeparOcto)
Cancer type: Breast Cancer
Variant class: ERBB2 amplification
Other identifiers: EudraCT Number: 2014-000619-14, GBG 84, GBG84, GeparOcto, TrialTroveID-208065
Population segments: Anemia, Cancer-related, HER2 negative, HER2 positive, Iron deficiency, Neoadjuvant, Stage II, Stage III, Triple receptor negative
Other inclusion criteria: ER negative, PR negative
Phase: III
Therapy: pertuzumab + trastuzumab + chemotherapy + ferric carboxymaltose
Country: Germany

NCT02514681
A Randomized, Open-label Phase III Trial to Evaluate the Efficacy and Safety of Pertuzumab Retreatment in Previously Pertuzumab, Trastuzumab and Chemotherapy Treated Her2-Positive Metastatic Locally Advanced and Metastatic Breast Cancer (Study of Perjeta Re-treatment for Clinical Outcomes) (PRECIOUS)
Cancer type: Breast Cancer
Variant class: ERBB2 amplification
Other identifiers: JBCRG-M05, PRECIOUS, TrialTroveID-262555, UMIN000018202, UMIN000021514
Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage I, Stage II, Stage III, Stage IV
Phase: III
Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy
Country: Japan
ERBB2 amplification (continued)

NCT02586025
A Randomized, Multicenter, Double-blind, Placebo-controlled, Phase III Study Evaluating Pertuzumab in Combination With Docetaxel and Trastuzumab as Neoadjuvant Therapy, and Pertuzumab in Combination With Trastuzumab as Adjuvant Therapy Following Surgery and Chemotherapy in Patients With Early-stage or Locally Advanced HER2-positive Breast Cancer

Cancer type: Breast Cancer
Variant class: ERBB2 amplification

Other identifiers: CTR20150679, TrialTroveID-266822, YO28762
Population segments: Adjuvant, HER2 positive, Neoadjuvant, Stage II, Stage III
Other inclusion criteria: ER positive/negative, PR positive/negative
Phase: III
Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo
Countries: China, Republic of Korea, Taiwan, Thailand

NCT01785420
A Phase III Double Blind Randomized Placebo Controlled Study of Trastuzumab as Short Duration Preoperative Therapy in Patients with HER2-neu Positive Operable Breast Cancer

Cancer type: Breast Cancer
Variant class: ERBB2 amplification

Other identifiers: TMH Project-982, TrialTroveID-181718
Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III
Phase: III
Therapy: trastuzumab
Country: India

NCT01875367
Clinical Trial to Evaluate Patient’s Preference of Subcutaneous Trastuzumab (SC) Versus Intravenous (IV) Administration in Patients With HER2 Positive Advanced Breast Cancer (ABC) Who Have Received Intravenous Trastuzumab at Least 4 Months and Without Disease Progression

Cancer type: Breast Cancer
Variant class: ERBB2 amplification

Other identifiers: ChangHER-SC, EudraCT Number: 2012-004928-38, GEICAM/2012-07, TrialTroveID-188333
Population segments: HER2 positive, Line of therapy N/A, Stage III, Stage IV
Phase: III
Therapy: trastuzumab
Country: Spain

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### ERBB2 amplification (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Study Description</th>
<th>Other identifiers</th>
<th>Population segments</th>
<th>Phase</th>
<th>Therapies</th>
<th>Country</th>
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<tbody>
<tr>
<td>NCT02040935</td>
<td>Homerus: A Local Open Label, Multicentre, Phase IIIb Study, Investigating Subcutaneous Trastuzumab Administered At Home With Single Injection Device In Patients With HER2-Positive Early Breast Cancer</td>
<td>EudraCT Number: 2013-000829-31, HOMERUS, ML28878, NL44120.056.13, TrialTroveID-200740</td>
<td>Adjuvant, HER2 positive, Line of therapy N/A, Neoadjuvant, Stage I, Stage II, Stage III</td>
<td>III</td>
<td>trastuzumab</td>
<td>Netherlands</td>
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<tr>
<td>NCT01950182</td>
<td>A Multicentre, Randomized Study of Trastuzumab Combined With Chemotherapy or Endocrine Therapy as the First Line Treatment for Patients With Metastatic Luminal B2 Breast Cancer Subtype</td>
<td>SYSUCC-002, TrialTroveID-194434</td>
<td>First line, HER2 positive, Stage IV</td>
<td>III</td>
<td>trastuzumab + chemotherapy, trastuzumab + hormone therapy</td>
<td>China</td>
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<tr>
<td>NCT00629278</td>
<td>SHORT-HER: Multicentric Randomised Phase III Trial of 2 Different Adjuvant Chemotherapy Regimens Plus 3 Vs 12 Months of Trastuzumab In Her2 Positive Breast Cancer Patients.</td>
<td>AOUMODENA-SHORT-HER, EU-20825, EudraCT Number: 2007-004326-25, FARM62MC97, SHORT-HER, Short-HER, Shorther 2007-004326-25, TrialTroveID-085109</td>
<td>Adjuvant, HER2 positive, Stage I, Stage II, Stage III</td>
<td>III</td>
<td>trastuzumab + hormone therapy + chemotherapy</td>
<td>Italy</td>
</tr>
</tbody>
</table>

**ONC16-: 0155**

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### ERBB2 amplification (continued)

**NCT01702571**
A Two-cohort, Open-label, Multicenter Study of Trastuzumab Emtansine (T-DM1) in HER2-positive Locally Advanced or Metastatic Breast Cancer Patients Who Have Received Prior Anti-HER2 and Chemotherapy-based Treatment.

- **Cancer type:** Breast Cancer
- **Variant class:** ERBB2 positive

- **Other identifiers:** CTR20150630, EudraCT Number: 2012-001628-37, IRAS ID: 109645, KAMILLA, MO28231, NCRN463, NL42030.031.12, PER-130-12, RECF1930, TrialTroveID-175473, UKCRN: 12866
- **Population segments:** First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
- **Phase:** III
- **Therapy:** ado-trastuzumab emtansine
- **Countries:** China, Thailand

**No NCT ID - see other identifier(s)**
Adjuvant Dynamic marker- Adjusted Personalized Therapy trial optimizing risk assessment and therapy response prediction in early breast cancer

- **Cancer type:** Breast Cancer
- **Variant class:** ERBB2 positive

- **Other identifiers:** ADAPT, ADAPT Umbrella, EudraCT Number 2011-001462-17, TrialTroveID-159300, WSG-AM06
- **Population segments:** Adjuvant, HER2 negative, HER2 positive, Stage I, Stage II, Triple receptor negative
- **Phase:** III
- **Therapies:** aromatase inhibitor, tamoxifen
- **Country:** Germany

**NCT02568839**
PREDIX HER2 - Neoadjuvant Response-guided Treatment of HER2 Positive Breast Cancer. Part of a Platform of Translational Phase II Trials Based on Molecular Subtypes

- **Cancer type:** Breast Cancer
- **Variant class:** ERBB2 positive

- **Other identifiers:** EudraCT Number: 2014-000808-10, PREDIX HER2, PREDIXHER2, TrialTroveID-243494
- **Population segments:** HER2 positive, Neoadjuvant, Stage II, Stage III
- **Phase:** II/III
- **Therapies:** ado-trastuzumab emtansine, pertuzumab + trastuzumab + chemotherapy
- **Country:** Sweden

**ONC16-: 0155**

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### ERBB2 amplification (continued)

**NCT02213744**  
A Randomized, Multicenter, Open Label Study of MM-302 Plus Trastuzumab vs. Chemotherapy of Physician’s Choice Plus Trastuzumab in Anthracycline Naive Patients With Locally Advanced/Metastatic HER2-Positive Breast Cancer  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 positive  
**Other identifiers:** 107006, 14-533, 2014-0670, 250781, 6894, 9785-CL-1121, EudraCT Number: 2014-003159-73, HERMIONE, MM-302-02-02-03, OSU-15168, REec-2015-1599, S14-01346, TrialTroveID-250781, VICCBRE1480  
**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV  
**Phase:** II/III  
**Therapy:** trastuzumab + chemotherapy  
**Countries:** Austria, Belgium, Canada, France, Germany, Italy, Spain, United States  
**US States:** AZ, CA, CO, CT, DC, FL, GA, IA, IL, IN, MA, MD, MI, MN, MO, NC, NJ, NY, OH, PA, SC, TN, TX, UT, VA, WA  
**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

**NCT02308020**  
A Phase II Study of Abemaciclib in Patients With Brain Metastases Secondary to Hormone Receptor Positive Breast Cancer  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Population segments:** CNS mets, First line, HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV  
**Other inclusion criteria:** ER positive, PR positive  
**Phase:** II  
**Therapy:** abemaciclib  
**Countries:** Australia, Austria, Belgium, Canada, France, Israel, Italy, Spain, United States  
**US States:** CA, CO, CT, DC, FL, GA, HI, KY, MA, MO, NC, OR, PA, TN, TX  
**US Contact:** Eli Lilly and Company [877-285-4559]

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**ERBB2 amplification (continued)**

<table>
<thead>
<tr>
<th>Study ID</th>
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| NCT02414646 | Adjuvant Ado-Trastuzumab Emtansine (T-DM1) for Older Patients With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer  
Cancer type: Breast Cancer  
Variant class: ERBB2 amplification |
| Other identifiers: 15-019, NCI-2015-00468, RU011301I, TrialTroveID-255420  
Population segments: Adjuvant, HER2 positive, Stage I, Stage II, Stage III  
Phase: II  
Therapy: ado-trastuzumab emtansine  
Country: United States  
US States: CA, IL, KS, MA, MI, MN, NC, NY, OH, VA  
US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts. |

| NCT02073487 | Randomized Open Label PhII Trial of Neoadjuvant Trastuzumab Emtansine (Te) in Combination w/Lapatinib (L) Followed by Abraxane (A) Compared w/ Trastuzumab Plus Pertuzumab Followed by Paclitaxel in Her 2 Neu Over-Expressed Breast Cancer Patients  
Cancer type: Breast Cancer  
Variant class: ERBB2 amplification |
| Other identifiers: 1013-0164, TEAL, TrialTroveID-203714  
Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III  
Phase: II  
Therapies: ado-trastuzumab emtansine + lapatinib + chemotherapy, pertuzumab + trastuzumab + chemotherapy  
Country: United States  
US State: TX  
US Contact: Houston Methodist Cancer Center [713-441-0629; ccresearch@houstonmethodist.org] |

| NCT01924351 | A Phase II Study of Stereotactic Radiosurgery Plus HER-2 Directed Therapy in HER2-positive Breast Cancer with Brain Metastasis  
Cancer type: Breast Cancer  
Variant class: ERBB2 amplification |
| Other identifiers: HP-00056720, TrialTroveID-192321  
Population segments: CNS mets, HER2 positive, Neoadjuvant, Stage IV  
Phase: II  
Therapy: ado-trastuzumab emtansine + lapatinib + pertuzumab + trastuzumab + chemotherapy + radiosurgery  
Country: United States  
US State: MD  
US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts. |

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## ERBB2 amplification (continued)

### NCT02326974
The Impact of HER2 Heterogeneity on the Treatment of Early-stage HER2-positive Breast Cancer: a Phase II Study of T-DM1 in Combination with Pertuzumab in the Preoperative Setting.

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** 14-409, TrialTroveID-249435  
**Population segments:** HER2 positive, Maintenance/Consolidation, Neoadjuvant, Stage 0, Stage I, Stage II, Stage III  
**Phase:** II  
**Therapy:** ado-trastuzumab emtansine + pertuzumab

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Country: United States  
US State: MA  
US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.
```

### NCT01042379
I-SPY 2 Trial (Investigation of Serial Studies to Predict Your Therapeutic Response With Imaging And moLecular Analysis 2)

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** 097517, 202755051910, 7518, ACRIN 6698 (Substudy), ACRIN-6698, CRC 10016, I-SPY 2 TRIAL, I-SPY2 TRIAL, NCI-2015-00014, STU 052011-089, TrialTroveID-120942  
**Population segments:** HER2 negative, HER2 positive, Neoadjuvant, Stage II, Stage III, Stage IV, Triple receptor negative  
**Other inclusion criteria:** ER positive/negative, PR positive/negative  
**Phase:** II  
**Therapies:** ado-trastuzumab emtansine + pertuzumab, ganetespib, ganitumab + metformin hydrochloride, MK-2206, MK-2206 + trastuzumab, pembrolizumab + chemotherapy, pertuzumab + trastuzumab, talazoparib + chemotherapy, trastuzumab + chemotherapy, trastuzumab + trebananib, trebananib

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Country: United States  
US States: AL, AZ, CA, CO, DC, FL, IL, MN, OR, PA, TX, WA  
US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.
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### ERBB2 amplification (continued)

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<th>Trial Title</th>
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<th>Variant class</th>
<th>Other identifiers</th>
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<th>Phase</th>
<th>Therapies</th>
<th>Country</th>
<th>US States</th>
<th>US Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01853748</td>
<td>A Randomized Phase II Study of Trastuzumab Emtansine (T-DM1) vs. Paclitaxel in Combination With Trastuzumab for Stage I HER2-Positive Breast Cancer (ATEMPT Trial)</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>00048638, 13-048, 137522, 14-221, 2013-0957, ATEMPT Trial, DFCI 13-048, ML28160, NCI-2013-01818, TBCRC 033, TrialTroveID-186443</td>
<td>Adjuvant, HER2 positive, Stage I</td>
<td>II</td>
<td>ado-trastuzumab emtansine, trastuzumab + chemotherapy</td>
<td>United States</td>
<td>CA, CT, DC, FL, ID, IL, IN, MA, MD, ME, MI, MN, MO, NC, NH, NJ, NY, OH, PA, TN, TX, WA</td>
<td>Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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<td>NCT02614794</td>
<td>Phase 2 Randomized, Double-Blinded, Controlled Study of ONT-380 vs Placebo in Combination With Capecitabine and Trastuzumab in Patients With Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>ONT-380-206, TrialTroveID-258510</td>
<td>CNS mets, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
<td>II</td>
<td>ARRY-380 + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo</td>
<td>Canada, United States</td>
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<td>Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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<tr>
<td>NCT01690325</td>
<td>Molecular Imaging for Response Assessment of Bevacizumab + Docetaxel as Neoadjuvant Chemotherapy in Primary Breast Cancer</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>EudraCT Number: 2009-013331-37, GALADON, TrialTroveID-154138, WSG-AM05</td>
<td>Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage III</td>
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<td>bevacizumab + chemotherapy, bevacizumab + trastuzumab + chemotherapy</td>
<td>Germany</td>
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#### ERBB2 amplification (continued)

<table>
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<tr>
<th>Study ID</th>
<th>Title</th>
<th>Cancer Type</th>
<th>Variant Class</th>
<th>Other Identifiers</th>
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<th>Therapy</th>
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<tr>
<td>NCT02260531</td>
<td>A Phase II Study of Cabozantinib Alone or in Combination With Trastuzumab in Breast Cancer Patients With Brain Metastases</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>14-359, NCI-2014-02365, TrialTroveID-218514</td>
<td>CNS mets, HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV, Triple receptor negative</td>
<td>II</td>
<td>cabozantinib + trastuzumab</td>
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<td>MA</td>
<td>Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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<tr>
<td>NCT02047747</td>
<td>A Phase II Study to Evaluate the Efficacy, Safety, and Central Nervous System (CNS) Pharmacokinetics of the HER Family Inhibitor Dacomitinib in Progressive Brain Metastases</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>130418, DP01-WS2043189, NCI-2014-00818, TrialTroveID-201579, UCSD 139418</td>
<td>CNS mets, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
<td>II</td>
<td>dacomitinib</td>
<td>United States</td>
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<tr>
<td>NCT01283789</td>
<td>Phase II Trial of Lapatinib and RAD-001 for HER2 Positive Metastatic Breast Cancer</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>12418, TrialTroveID-141401</td>
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<td>everolimus + lapatinib</td>
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<td>KS</td>
<td>Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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### ERBB2 amplification (continued)

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<th>Trial Identifier</th>
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<td>NCT01305941</td>
<td>A Phase II Study Evaluating The Efficacy And Tolerability Of Everolimus (RAD001) In Combination With Trastuzumab And Vinorelbine In The Treatment Of Progressive HER2-Positive Breast Cancer Brain Metastases</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>11-0242, LCCC 1025, LCCC1025, TrialTroveID-143197, VICCBRE1304</td>
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<td>everolimus + trastuzumab + chemotherapy</td>
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<tr>
<td>NCT01730677</td>
<td>Randomized Phase II Study of Lapatinib Plus Vinorelbine Versus Vinorelbine in Patients With HER2 Positive Metastatic Breast Cancer Progressed After Lapatinib and Trastuzumab Treatment</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>NCCCTS-11-583, TrialTroveID-177908</td>
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<td>lapatinib + chemotherapy</td>
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<tr>
<td>NCT02338245</td>
<td>Randomized Phase IIA/IIB Study to Compare the Efficacy and Safety of ASLAN001 + Capecitabine to Lapatinib + Capecitabine in Patients With HER2-Positive MBC That Has Failed on Prior Trastuzumab Therapy</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>2015-CT0298, ASLAN001-003, PHRR150911-001084, TrialTroveID-250457</td>
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<td>lapatinib + chemotherapy, varlitinib + chemotherapy</td>
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</table>

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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<th>Trial ID</th>
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<tr>
<td>NCT01622868</td>
<td>Phase II Randomized Study of Whole Brain Radiotherapy/Stereotactic Radiosurgery in Combination With Concurrent Lapatinib in Patients With Brain Metastasis From HER2-Positive Breast Cancer: A Collaborative Study of NRG Oncology and KROG</td>
<td>20140570, KROG1103, NCI-2012-01977, RTOG 1119, RTOG-1119, TrialTroveID-169961</td>
<td>CNS mets, First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
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<td>Lapatinib + radiation therapy</td>
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<td>Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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<tr>
<td>NCT01873833</td>
<td>Phase II Trial of Metronomic Capecitabine and Cyclophosphamide With Lapatinib and Trastuzumab in Patients With HER2 Positive Metastatic Breast Cancer Who Have Progressed on a Previous Trastuzumab-Based Regimen</td>
<td>1B-12-10, NCI-2013-01086, TrialTroveID-188235</td>
<td>HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
<td>II</td>
<td>Lapatinib + trastuzumab + chemotherapy</td>
<td>United States</td>
<td>CA</td>
<td>USC Norris Comprehensive Cancer Center Recruiting - Kristy A. Watkins [323-865-0452; <a href="mailto:Kristy.Watkins@med.usc.edu">Kristy.Watkins@med.usc.edu</a>]</td>
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<tr>
<td>NCT01891357</td>
<td>A Multicenter Site, Open Label, Phase II Trial to Validate Predictive Markers for the Response Evaluation of a Combined Chemo-immunotherapy in Patients With HER2-positive Early Breast Cancer</td>
<td>EudraCT Number: 2012-003679-21, Neo-PREDICT-HER2, TrialTroveID-189633, WSG-AM07, WSG-AM07 (Neo-PREDICT-HER2)</td>
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<tr>
<td>Therapy: lapatinib + trastuzumab + fulvestrant</td>
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<tr>
<td>Phase: II</td>
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<tr>
<td>Therapies: lapatinib + trastuzumab, trastuzumab + chemotherapy</td>
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<td>Phase: II</td>
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</tr>
<tr>
<td>Therapy: nelipepimut-S + sargramostim + trastuzumab</td>
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<td>Country: United States</td>
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<td>US States: CA, CO, DC, FL, IL, IN, MD, NM, NY, TX, VA, WA, WI</td>
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<td>US Contact: Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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### ERBB2 amplification (continued)

| NCT01494662 | **A Phase II Trial of HKI-272 (Neratinib) for Patients With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer and Brain Metastases**  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** 11-344, TBCRC 022, TrialTroveID-158829, UMCC 2012.034  
**Population segments:** CNS mets, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV  
**Phase:** II  
**Therapies:** neratinib, neratinib + chemotherapy, neratinib + surgical intervention, neratinib + trastuzumab  
**Country:** United States  
**US States:** CA, DC, MA, MD, MI, NC, PA, TX  
**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts. |
|---|---|
| NCT02448420 | **PATRICIA: A Phase II Clinical Trial of Combined Palbociclib and Trastuzumab, With or Without Letrozole, in Post-menopausal Patients With Previously-treated Locally Advanced or Metastatic HER2-positive Breast Cancer**  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** EudraCT Number: 2014-005006-38, PATRICIA, REec-2015-1446, SOLTI-1303, TrialTroveID-256931  
**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV  
**Other inclusion criteria:** ER negative, PR positive  
**Phase:** II  
**Therapy:** palbociclib + trastuzumab  
**Country:** Spain |
### ERBB2 amplification (continued)

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<td><strong>A Randomized, Two-arm, Open-label, Multicenter Phase II Trial Assessing the Efficacy and Safety of Pertuzumab Given in Combination With Trastuzumab Plus an Aromatase Inhibitor in First Line Patients With HER2-positive and Hormone Receptor-positive Advanced (Metastatic or Locally Advanced) Breast Cancer.</strong></td>
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<td><strong>Cancer type:</strong> Breast Cancer</td>
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<td><strong>Variant class:</strong> ERBB2 amplification</td>
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<td><strong>Other identifiers:</strong> 201202149, CTRI/2012/08/002900, EudraCT Number: 2011-002132-10, GEICAM/2011-01, i1680, MO27775, NCN335, PERTAIN, TrialTrovelID-158026, UKCRN 10947</td>
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<td><strong>Other inclusion criteria:</strong> ER positive and/or PR positive</td>
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<td><strong>Phase:</strong> II</td>
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<tr>
<td><strong>Therapies:</strong> pertuzumab + trastuzumab + aromatase inhibitor, trastuzumab + aromatase inhibitor</td>
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<td><strong>Countries:</strong> Spain, United States</td>
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<tr>
<td><strong>US Contact:</strong> Reference Study ID Number: MO27775 [888-662-6728; <a href="mailto:genentechclinicaltrials@druginfo.com">genentechclinicaltrials@druginfo.com</a>]</td>
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<tr>
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<tr>
<td><strong>A Phase II Study Of Eribulin In Combination With Trastuzumab And Pertuzumab As First-Line Therapy For Metastatic HER2-Positive Breast Cancer</strong></td>
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<td><strong>Cancer type:</strong> Breast Cancer</td>
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<td><strong>Variant class:</strong> ERBB2 amplification</td>
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<td><strong>Other identifiers:</strong> SBCCSG-36, TrialTrovelID-275562, UMIN000021585</td>
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<td><strong>Phase:</strong> II</td>
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<tr>
<td><strong>Therapy:</strong> pertuzumab + trastuzumab + chemotherapy</td>
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<td><strong>Country:</strong> Japan</td>
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<tr>
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<tbody>
<tr>
<td><strong>A phase II study of eribulin in combination with pertuzumab and trastuzumab for advanced or recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer SONG-02</strong></td>
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<td><strong>Cancer type:</strong> Breast Cancer</td>
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<td><strong>Other identifiers:</strong> SONG-02, TrialTrovelID-209955, UMIN000014107</td>
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<tr>
<td><strong>Therapy:</strong> pertuzumab + trastuzumab + chemotherapy</td>
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### ERBB2 amplification (continued)

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<tr>
<td>A Study of Eribulin in Combination with Trastuzumab and Pertuzumab for Advanced or Recurrent Human Epidermal Growth Factor Receptor 2 (HER2)-positive Breast Cancer</td>
<td>JBCRG-M03, TrialTroveID-196752, UMIN000012232</td>
<td>First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
<td>II</td>
<td>pertuzumab + trastuzumab + chemotherapy</td>
<td>Japan</td>
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<td>A phase II trial of pertuzumab and trastuzumab in combination with capecitabine in patients with metastatic breast cancer who received prior trastuzumab combination chemotherapy.</td>
<td>TrialTroveID-196596, UMIN000012208</td>
<td>HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
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<tr>
<td>A Phase II Study of Pertuzumab + Trastuzumab + Capecitabine in Patients with Taxans and Trastuzumab Refractory for Advanced or Recurrent Breast Cancer</td>
<td>SBCCSG-33, TrialTroveID-195194, UMIN000012030</td>
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<td>Japan</td>
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<tr>
<td>Phase II Trial of Pertuzumab plus Trastuzumab plus Docetaxel for HER2-Positive Metastatic Breast Cancer that Progressed During Prior Trastuzumab Therapy</td>
<td>CYBORG-002, TrialTroveID-198231, UMIN000012452</td>
<td>HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
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<td>pertuzumab + trastuzumab + chemotherapy</td>
<td>Japan</td>
</tr>
</tbody>
</table>

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**ERBB2 amplification (continued)**

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<tr>
<td>Phase II Prospective Open Label Single Arm Study of Pertuzumab, Trastuzumab, and Nab-Paclitaxel in Patients With HER-2 Positive Metastatic Breast Cancer</td>
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<td>Cancer type: Breast Cancer</td>
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<td>Variant class: ERBB2 amplification</td>
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<tr>
<td>Population segments: First line, HER2 positive, Stage IV</td>
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<td>Phase: II</td>
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<tr>
<td>Therapy: pertuzumab + trastuzumab + chemotherapy</td>
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<td>Country: United States</td>
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<td>US Contact: Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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<td>Single Arm, Neoadjuvant, Phase II Trial of Pertuzumab and Trastuzumab Administered Concomitantly With Weekly Paclitaxel and FEC for Clinical Stage I-II HER2-Positive Breast Cancer</td>
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<td>Population segments: Adjuvant, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III</td>
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<td>Phase: II</td>
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<tr>
<td>Therapy: pertuzumab + trastuzumab + chemotherapy</td>
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<td>Country: United States</td>
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<tr>
<td>A Phase II Study of Eribulin Mesylate in Combination with Trastuzumab and Pertuzumab in Women with Metastatic, Unresectable Locally Advanced, or Locally Recurrent Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer</td>
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<tr>
<td>Variant class: ERBB2 amplification</td>
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<td>Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
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<td>Phase: II</td>
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<tr>
<td>Therapy: pertuzumab + trastuzumab + chemotherapy</td>
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<td>Country: United States</td>
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<td>US State: MA</td>
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<td>US Contact: Multiple contacts: See <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> for complete list of contacts.</td>
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## ERBB2 amplification (continued)

### NCT02252887
- **Phase** II Study of Gemcitabine, Trastuzumab, and Pertuzumab in the Treatment of Metastatic HER2-Positive Breast Cancer After Prior Trastuzumab/Pertuzumab-Based Therapy
  - **Cancer type**: Breast Cancer
  - **Variant class**: ERBB2 amplification
  - **Population segments**: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV
  - **Phase**: II
  - **Therapy**: pertuzumab + trastuzumab + chemotherapy
  - **Country**: United States
  - **US States**: CT, NJ, NY
  - **US Contact**: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.
  - **Other identifiers**: 14-124, NCI-2015-00078, TrialTroveID-217944

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- Multicenter Phase II trial of Combination Therapy Using Abraxane and Trastuzumab +/- Pertuzumab For HER2-Positive Locally Advanced or Metastatic Breast Cancer
  - **Cancer type**: Breast Cancer
  - **Variant class**: ERBB2 amplification
  - **Population segments**: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
  - **Phase**: II
  - **Therapies**: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy
  - **Country**: Japan
  - **Other identifiers**: TrialTroveID-158358, UMIN000006838

### NCT02345772
- Neoadjuvant Hormonal Therapy Combined With Chemoimmunotherapy (Taxotere, Trastuzumab and Pertuzumab) in Patients With HER2-positive and ER-Positive Breast Cancer (NeoHTTP Study)
  - **Cancer type**: Breast Cancer
  - **Variant class**: ERBB2 amplification
  - **Population segments**: HER2 positive, Neoadjuvant, Stage II, Stage III
  - **Phase**: II
  - **Therapy**: pertuzumab + trastuzumab + fulvestrant + chemotherapy
  - **Country**: United States
  - **US State**: AZ
  - **US Contact**: Research Nurse Coordinator [623-207-3000; Westerntrials@ctca-hope.com]
  - **Other identifiers**: NeoHTTP, TrialTroveID-251024, WIRB 20140462

DISCLAIMER: The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2016.09(002).
**ERBB2 amplification (continued)**

**NCT02411344**  
**PerTuzumab-trastuzumab Plus Letrozole In Endocrine Sensitive Breast Cancer: a Phase II neoAdjuvant Study**  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** AS.T.R.O.BC01-13, AS.TRO BC01-13, EudraCT Number: 2013-002662-40, PER-ELISA, TrialTroveID-255149  
**Population segments:** HER2 positive, Neoadjuvant, Stage II, Stage III  
**Other inclusion criteria:** ER positive and/or PR positive  
**Phase:** II  
**Therapy:** pertuzumab + trastuzumab + letrozole  
**Country:** Italy

**NCT01597414**  
**Pertuzumab + Trastuzumab (PH) Versus PH Plus Metronomic Chemotherapy (PHM) in the Elderly HER2+ Metastatic Breast Cancer Population Who May Continue on T-DM1 Alone Following Disease Progression While on PH / PHM: an Open-label Multicentre Randomized Phase II Selection Trial of the EORTC Elderly Task Force and Breast Cancer Group**  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** 126320, 14/WS/1107, 75111-10114, CTBE2013000218, EORTC 75111, EORTC-75111-10114, EORTC-75111-10114-ETF-BCG - 10114, EudraCT Number: 2011-006342-32, ML28116, MREC N° 14-WS-1107, TrialTroveID-167657, UKCRN ID 18430  
**Population segments:** First line, HER2 positive, Stage IV  
**Phase:** II  
**Therapies:** pertuzumab + trastuzumab, pertuzumab + trastuzumab + chemotherapy  
**Countries:** Belgium, France, Italy, Portugal

**NCT02659514**  
**A Phase 2 Study of Poziotinib in Patients With HER2-Positive Metastatic Breast Cancer (MBC) Who Have Received Prior HER2 Regimens for MBC**  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** NCI-2016-00645, SPI-POZ-201, TrialTroveID-253276  
**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV  
**Phase:** II  
**Therapy:** poziotinib  
**Country:** United States  
**US States:** CA, NY  
**US Contact:** Medical Director [949-743-9267; spi-poiz-201@sppirx.com]

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**ONC16- 0155**  
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Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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### ERBB2 amplification (continued)

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<tr>
<td>Phase II Study of Neoadjuvant Chemotherapy with Docetaxel, Carboplatin, and Trastuzumab for Operable Her2-positive Breast Cancer Patients.</td>
<td>Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III</td>
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<tr>
<td><strong>Variant class:</strong> ERBB2 amplification</td>
<td><strong>Therapy:</strong> trastuzumab + chemotherapy</td>
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<tr>
<td>Safety study of q3w S-1 in combination with q3w trastuzumab for HER2 positive metastatic breast cancer</td>
<td>Population segments: HER2 positive, Line of therapy N/A, Stage IV</td>
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<td><strong>Phase:</strong> II</td>
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<td><strong>Therapy:</strong> trastuzumab + chemotherapy</td>
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<td>Phase II study of neoadjuvant chemotherapy with the nab Paclitaxel And Trastuzumab followed by FEC for the HER2-positive resectable primary breast cancer</td>
<td>Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III</td>
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<td><strong>Phase:</strong> II</td>
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<tr>
<td><strong>Variant class:</strong> ERBB2 amplification</td>
<td><strong>Therapy:</strong> trastuzumab + chemotherapy</td>
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<tr>
<td>Multicenter phase II trial of neoadjuvant chemotherapy with trastuzumab, docetaxel, and carboplatin for HER2-positive operable breast cancer: KBOG-1204 trial</td>
<td>Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III</td>
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### ERBB2 amplification (continued)

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<tr>
<td>The safety and efficacy trial of nab-paclitaxel and trastuzumab as neoadjuvant chemotherapy for HER2-positive breast cancer</td>
<td>TrialTrove-ID200533, UMIN000012798</td>
<td>HER2 positive, Neoadjuvant, Stage II, Stage III</td>
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<td>Phase II Study Of Neoadjuvant Nab-paclitaxel And Trastuzumab For ER Negative And HER2 Positive Breast Cancer</td>
<td>TrialTroveID-268560, UMIN000019616</td>
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<td>II</td>
<td>trastuzumab + chemotherapy</td>
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<tr>
<td>A feasibility study of sequential Anthracycline-based regimen and Nab-Paclitaxel / Trastuzumab followed by Trastuzumab as postoperative adjuvant chemotherapy for Her 2 positive breast cancer (SBCCSG-22)</td>
<td>SBCCSG-22, TrialTroveID-164135, UMIN000006085</td>
<td>Adjuvant, HER2 positive, Stage I, Stage II, Stage III</td>
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<td>Country: Japan</td>
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<td>Neoadjuvant trastuzumab and nab-paclitaxel for HER2 positive breast cancer</td>
<td>TrialTroveID-152411, UMIN000005210</td>
<td>HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III</td>
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<td>trastuzumab + chemotherapy</td>
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### ERBB2 amplification (continued)

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<td>NCT02510781</td>
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<td>HER2 positive, Neoadjuvant, Stage II, Stage III</td>
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<tr>
<td>NCT02598310</td>
<td>Phase II Study of Neoadjuvant Nab-paclitaxel (PTX) and Trastuzumab for ER Negative and HER2 Positive Breast Cancer</td>
<td>Breast Cancer</td>
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<td>OMC BC-04, TrialTroveID-267504</td>
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<td>ER negative</td>
<td>II</td>
<td>trastuzumab + chemotherapy</td>
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<tr>
<td>NCT02488564</td>
<td>Clinical and Traslational Phase II Study of Liposomal Doxorubicin plus Docetaxel and Trastuzumab with Metformin as Primary Systemic Therapy for Operable and Locally Advanced Recombinant Human ErB-2 HER2 Positive Breast Cancer.</td>
<td>Breast Cancer</td>
<td>ERBB2 amplification</td>
<td>EudraCT Number: 2014-002602-20, IRST174.09, met-HEReMYTA, TrialTroveID-253444</td>
<td>First line, HER2 positive, Stage II, Stage III</td>
<td>II</td>
<td>trastuzumab + chemotherapy + metformin hydrochloride</td>
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<td>No NCT ID</td>
<td>Ki67 index guided selection of preoperative chemotherapy for HER2 positive breast cancer - a randomized phase II trial.</td>
<td>Breast Cancer</td>
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<td>TrialTroveID-160851, UMIN000007074</td>
<td>HER2 positive, Neoadjuvant, Stage II, Stage III</td>
<td>II</td>
<td>trastuzumab + chemotherapy + surgical intervention</td>
<td>Japan</td>
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</table>

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### ERBB2 amplification (continued)

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<tr>
<td>Phase II study of preoperative treatment of inflammatory breast cancer with bevacizumab in combination with weekly carboplatin and paclitaxel + or - trastuzumab and metronomic cyclophosphamide and endocrine therapy.</td>
<td>Population segments: HER2 negative, HER2 positive, Neoadjuvant, Stage III</td>
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<td>Cancer type: Breast Cancer</td>
<td>Other inclusion criteria: ER positive/negative, PR positive/negative</td>
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<td>Therapies: bevacizumab + chemotherapy, bevacizumab + trastuzumab + chemotherapy</td>
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<td>Reinduction with lapatinib followed by retreatment with trastuzumab-based therapy after disease progression multi-HER2 targeted therapies in HER2-positive metastatic breast cancer.</td>
<td>Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
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<td>Phase II Trial of the Cyclin-Dependent Kinase Inhibitor PD 0332991 in Patients With Cancer</td>
<td>Population segments: HER2 negative, HER2 positive, Metastatic, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative</td>
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<td>Other inclusion criteria: ER positive/negative, PR positive/negative</td>
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<td>Variant class: ERBB2 positive</td>
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<td>Therapies: palbociclib, palbociclib + trastuzumab</td>
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<td>US State: PA</td>
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<td>US Contact: Peter O'Dwyer [855-216-0098; <a href="mailto:PennCancerTrials@emergingmed.com">PennCancerTrials@emergingmed.com</a>]</td>
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ERBB2 amplification (continued)

**NCT01796197**
Phase II Trial of Paclitaxel Combined With Trastuzumab and Pertuzumab as Pre-Operative Therapy for Inflammatory Breast Cancer

*Cancer type:* Breast Cancer

*Variant class:* ERBB2 positive

*Other identifiers:* 12-497, TrialTroveID-182381

*Population segments:* Adjuvant, HER2 positive, Maintenance/Consolidation, Neoadjuvant, Stage I, Stage II, Stage III, Stage IV

*Phase:* II

*Therapy:* pertuzumab + trastuzumab + chemotherapy

*Country:* United States

*US State:* MA

*US Contact:* Dr. Beth Overmoyer [617-632-4056; bovermoyer@partners.org]

**NCT02436993**
A Phase II Study of Breast Cancer Treatment Using Weekly Carboplatin + Paclitaxel With Pertuzumab + Trastuzumab (HER2+) or Bevacizumab (HER2-) in the Neoadjuvant Setting

*Cancer type:* Breast Cancer

*Variant class:* ERBB2 positive

*Other identifiers:* 2015-1888, TrialTroveID-257064, UCI 14-67

*Population segments:* HER2 negative, HER2 positive, Neoadjuvant, Stage I

*Phase:* II

*Therapy:* pertuzumab + trastuzumab + chemotherapy

*Country:* United States

*US State:* CA

*US Contact:* UC Irvine Health Chao Family Comprehensive Cancer Center [877-827-8839; UCstudy@uci.edu]

**NCT02624973**
Personalized Treatment of High-risk mammary Cancer - the PETREMAC Trial

*Cancer type:* Breast Cancer

*Variant class:* ERBB2 positive

*Other identifiers:* 2015/8463, PETREMAC, TrialTroveID-269482

*Population segments:* Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage IV, Triple receptor negative

*Other inclusion criteria:* TP53 wild type

*Phase:* II

*Therapy:* pertuzumab + trastuzumab + hormone therapy + chemotherapy + radiation therapy

*Country:* Norway

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### ERBB2 amplification (continued)

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<td><strong>NCT01817452</strong></td>
<td>A Prospective, Randomized Multicenter, Open-label Comparison of Preoperative Combination of Trastuzumab and Pertuzumab With or Without Concurrent Taxane Chemotherapy Given for Twelve Weeks in Patients With Operable HER2+/HR- Breast Cancer Within the ADAPT Protocol</td>
<td>ADAPT HER2+/HR-, EudraCT Number: 2011-001462-17, TrialTroveID-181371, WSG-AM06 / ADAPT HER2+/HR-</td>
<td>HER2 positive, Neoadjuvant, Stage I, Stage II</td>
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<td>pertuzumab + trastuzumab, pertuzumab + trastuzumab + chemotherapy</td>
<td>Germany</td>
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<tr>
<td><strong>No NCT ID - see other identifier(s)</strong></td>
<td>Phase II Study of Epirubicin, Cisplatin and 5'-Fluorouracil Continuous Infusion (ECF) Followed by Weekly Paclitaxel in Combination with Metronomic Cyclophosphamide + or - Trastuzumab as Preoperative Treatment in Locally Advanced Breast Carcinoma ER and Pgr Negative</td>
<td>EudraCT Number: 2009-012048-18, IEO S479/209, S479/209, TrialTroveID-123950</td>
<td>HER2 negative, HER2 positive, Neoadjuvant, Stage III</td>
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<td><strong>No NCT ID - see other identifier(s)</strong></td>
<td>Pilot study of low-dose Nab-paclitaxel as adjuvant chemotherapy in patients with breast cancer</td>
<td>TrialTroveID-195469, UMIN000012047</td>
<td>(N/A), Adjuvant, HER2 negative, HER2 positive</td>
<td>II</td>
<td>trastuzumab + chemotherapy</td>
<td>Japan</td>
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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
A Phase II Study of Metronomic Oral Chemotherapy with Cyclophosphamide plus Capecitabine in combination with Herceptin to treat HER2 positive Advanced Breast Cancer
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: 2905, EudraCT Number: 2009-017083-16, GOIM2905, TrialTroveID-121640

Population segments: First line, HER2 positive, Stage III, Stage IV
Phase: II
Therapy: trastuzumab + chemotherapy
Country: Italy

No NCT ID - see other identifier(s)
Phase II study of q3w nab-paclitaxel in combination with q3w trastuzumab for HER2 positive metastatic breast cancer.
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: Nature study, TrialTroveID-164392, UMIN000006547

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV
Phase: II
Therapy: trastuzumab + chemotherapy
Country: Japan

No NCT ID - see other identifier(s)
A Phase II study of neoadjuvant epirubicin/cyclophosphamide (EC) followed by weekly nanoparticle albumin-bound paclitaxel with trastuzumab for HER2-positive breast cancer
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: TrialTroveID-208244, UMIN000013886

Population segments: HER2 positive, Neoadjuvant, Stage II, Stage III
Phase: II
Therapy: trastuzumab + chemotherapy
Country: Japan

No NCT ID - see other identifier(s)
Combination therapy of Eribulin with Trastuzumab for HER2 positive metastatic breast cancer
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: SBP04, TrialTroveID-204331, UMIN000009296

Population segments: First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV
Phase: II
Therapy: trastuzumab + chemotherapy
Country: Japan

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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<tr>
<th>Study Details</th>
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<td><strong>trastuzumab + chemotherapy</strong></td>
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<td>Pegylated Liposomal Doxorubicin Hydrochloride and Trastuzumab in the First Line Treatment of Metastatic HER2 Positive Breast Carcinoma in Elderly Women</td>
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<td>Phase II study of the combination of Eribulin and Trastuzumab Evaluating Efficacy and Safety in Patients with advanced/recurrent HER2-positive breast cancer</td>
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<td><strong>trastuzumab + chemotherapy</strong></td>
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<td>Evaluation of efficacy and safety of combination therapy with trastuzumab and eribulin for HER2-positive inoperableness or metastatic breast cancer</td>
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<td>Phase II Study of low-dose Nab-paclitaxel for Advanced Breast Cancer</td>
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### ERBB2 amplification (continued)

**NCT00618657**  
**A Phase II Study of Breast Cancer Treatment Using Weekly Carboplatin + Nab-paclitaxel, Plus Trastuzumab (HER2+) or Bevacizumab (HER2-) in the Neoadjuvant Setting**  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 positive  
**Other identifiers:** 2007-6084, 20990234, HS#2007-6084, NCI-2010-00155, TrialTroveID-084377, UCI 07-61, UCI-07-61  
**Population segments:** HER2 negative, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III  
**Phase:** II  
**Therapy:** trastuzumab + chemotherapy  
**Country:** United States  
**US State:** CA  
**US Contact:** Dr. Rita S. Mehta [877-827-8839; UCstudy@uci.edu]

**NCT01387295**  
**Intra-hepatic Chemotherapy With Oxaliplatin Every Second Week in Combination With Systemic Capetabine in Patient With Non-resectable Liver Metastases From Breast Cancer A Phase II Trial in Patients With Limited Extrahepatic Disease**  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 positive  
**Other identifiers:** EudraCT Number: 2009-014821-17, MA 0918, TrialTroveID-149256  
**Population segments:** First line, HER2 positive, Liver mets, Second line or greater/ Refractory/Relapsed, Stage IV  
**Phase:** II  
**Therapy:** trastuzumab + chemotherapy  
**Country:** Denmark

**NCT01387373**  
**Intra-hepatic Chemotherapy with Oxaliplatin Every Second Week in Combination with Systemic Capecitabine in Patient with Non-resectable Liver Metastases from Breast Cancer. A Phase II Trial**  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 positive  
**Other identifiers:** EudraCT Number: 2009-014863-37, MA 0919, TrialTroveID-149349  
**Population segments:** First line, HER2 positive, Liver mets, Second line or greater/ Refractory/Relapsed, Stage III, Stage IV  
**Phase:** II  
**Therapy:** trastuzumab + chemotherapy  
**Country:** Denmark

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ERBB2 amplification (continued)

NCT01750073
A Phase II Study Of Neoadjuvant Chemotherapy With And Without Trastuzumab In Patients With Breast Cancer
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: 264-12, NCI-2012-01372, TrialTroveID-179329
Population segments: Adjuvant, HER2 negative, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative
Phase: II
Therapy: trastuzumab + chemotherapy
Country: United States
US State: NE
US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT01959490
Next Generation Sequencing to Evaluate Breast Cancer Subtypes and Genomic Predictors of Response to Therapy in the Preoperative Setting for Stage II-III Breast Cancer
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: CASE 14112, CASE14112, NCI-2013-01422, TrialTroveID-195323
Population segments: First line, HER2 negative, HER2 positive, Stage II, Stage III
Phase: II
Therapy: trastuzumab + chemotherapy
Country: United States
US State: OH
US Contact: Dr. Lyndsay N. Harris [216-844-3951; lyndsay.harris@uhhospitals.org]

NCT01472146
Phase II Clinical Trial of Neoadjuvant Treatment With Zolendronic Acid Plus Anthracycline and Taxane in Locally Advanced Breast Cancer
Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: 154/10 - Zo-NANTAX, TrialTroveID-156985, Zo-neo2011, ZoNantax
Population segments: HER2 positive, Neoadjuvant, Stage II, Stage III
Phase: II
Therapy: trastuzumab + chemotherapy + zoledronic acid
Country: Brazil
### ERBB2 amplification (continued)

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<th>Study ID</th>
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<th>Population segments</th>
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<td>A Phase II Neoadjuvant Trial of Concurrent Trastuzumab, Paclitaxel and Endocrine Therapy in Women with HER2-Positive and Hormone Receptor-Positive Breast Cancer</td>
<td>Other identifiers: HERPLET, TrialTroveID-175990, UMIN000009108</td>
<td>Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III</td>
<td>Other inclusion criteria: ER positive and/or PR positive</td>
<td>Phase: II</td>
<td>Therapy: trastuzumab + hormone therapy + chemotherapy</td>
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<td>No NCT ID - see other identifier(s)</td>
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<td>A Phase II neoadjuvant trial of concurrent trastuzumab and aromatase inhibitor in postmenopausal women with HER2-positive and hormone receptor-positive breast cancer.</td>
<td>Other identifiers: TrialTroveID-162796, UMIN000007353</td>
<td>Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III</td>
<td>Other inclusion criteria: ER positive and/or PR positive</td>
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<td>Early Cardiac Changes During Anthracycline and/or Trastuzumab Therapy in Breast Cancer</td>
<td>Other identifiers: ACTRN12611000153910, TrialTroveID-144193, U1111-1119-2755</td>
<td>Population segments: First line, HER2 positive, Stage 0, Stage I, Stage II</td>
<td>Phase: II</td>
<td>Therapies: trastuzumab, trastuzumab + chemotherapy</td>
<td>Australia</td>
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<td>NCT01702558</td>
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<td>Population segments: First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
<td>Phase: I/II</td>
<td>Therapies: ado-trastuzumab emtansine, ado-trastuzumab emtansine + chemotherapy</td>
<td>Argentina, Brazil, France, Germany, Italy, Serbia, Slovakia</td>
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### ERBB2 amplification (continued)

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<td>Phase I/II Single-arm Trial Evaluating the Combination of Lapatinib, Everolimus and Capecitabine for the Treatment of Patients With HER2-positive Metastatic Breast Cancer With CNS Progression After Trastuzumab</td>
<td><strong>Population segments:</strong> CNS mets, First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
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<td><strong>Cancer type:</strong> Breast Cancer</td>
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<td><strong>Variant class:</strong> ERBB2 amplification</td>
<td><strong>Therapy:</strong> everolimus + lapatinib + chemotherapy</td>
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<td><strong>Country:</strong> United States</td>
<td><strong>US State:</strong> CA</td>
</tr>
<tr>
<td><strong>US Contact:</strong> Sara A. Hurvitz [888-798-0719; <a href="mailto:shurvitz@mednet.ucla.edu">shurvitz@mednet.ucla.edu</a>]</td>
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<tr>
<td>Phase I/II Study Eribulin Mesylate and Lapatinib for Metastatic in Patients With Human Epidermal Growth Factor receptor 2-Positive Breast Cancer Previously Treated With an Anthracycline, Taxane and Trastuzumab.</td>
<td><strong>Population segments:</strong> HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
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<td><strong>Cancer type:</strong> Breast Cancer</td>
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<td><strong>Variant class:</strong> ERBB2 amplification</td>
<td><strong>Therapy:</strong> lapatinib + chemotherapy</td>
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<td>An Open-label, Multi-center, Dose-escalation, Safety and Tolerability Phase I/II Study of MCLA-128 for the Treatment of Solid Tumors</td>
<td><strong>Population segments:</strong> Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
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ERBB2 amplification (continued)

**NCT02129556**  
A Phase Ib/II Trial Evaluating the Efficacy of MK-3475 and Trastuzumab in Patients With Trastuzumab-resistant, HER2-positive Metastatic Breast Cancers  
Cancer type: Breast Cancer  
Variant class: ERBB2 amplification  
Other identifiers: BIG 4-13, EudraCT Number: 2013-004770-10, IBCSG 45-13, IBCSG 45-13 PANACEA, IBCSG 45-13/BIG 4-13, PANACEA, TrialTroveID-208268  
Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV  
Phase: I/II  
Therapy: pembrolizumab + trastuzumab  
Countries: Australia, Austria, Belgium, France, Italy

**NCT02139358**  
Phase I/IIa Trial of Gemcitabine Plus Trastuzumab and Pertuzumab in Previously Treated Metastatic HER2+ Breast Cancer  
Cancer type: Breast Cancer  
Variant class: ERBB2 amplification  
Other identifiers: 17656, MCC-17656, ML28939, TrialTroveID-208961  
Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV  
Phase: I/II  
Therapy: pertuzumab + trastuzumab + chemotherapy  
Country: United States  
US State: FL  
US Contact: Deanna Hogue [813-745-8304; deanna.hogue@moffitt.org]

**NCT01325207**  
Phase I/II Dose Escalation Trial to Assess Safety of Intrathecal Trastuzumab for the Treatment of Leptomeningeal Metastases in HER2 Positive Breast Cancer  
Cancer type: Breast Cancer  
Variant class: ERBB2 amplification  
Other identifiers: 13-159, AAAO4157, H4320//NU 10C03, MSKCC 12-123, NCI:2011-00110, NU 10C03, STU00040150, STU00040150-M0D0003, TrialTroveID-144325  
Population segments: CNS mets, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV  
Phase: I/II  
Therapy: trastuzumab  
Country: United States  
US States: CA, IL, MA, NY, TX  
US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

**ONC16-**: 0155  
www.oncologica.com  
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<td>Phase I/II Study of Safety and Efficacy of Intrathecal Trastuzumab Administration in Metastatic HER2 Positive Breast Cancer Patients Developing Carcinomatous Meningitis</td>
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<td>Phase I/II Study of Expanded, Activated Autologous Natural Killer Cell Infusions With Trastuzumab for Patients With HER2+ Breast and Gastric Cancer</td>
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<td>Phase Ib Dose-confirmation Study of ASLAN001 Combined With Weekly Paclitaxel and Carboplatin in Advanced Solid Tumours, Followed by an Open-label Phase II Study in Patients With Stage I-III HER2 Positive Breast Cancer</td>
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<td>Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III</td>
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## ERBB2 amplification (continued)

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<td>NCT02236000</td>
<td>A Phase Ib/II Dose-Escalation Study Evaluating the Combination of Trastuzumab Emtansine (T-DM1) With Neratinib in Women With Metastatic HER2-Positive Breast Cancer</td>
<td>Breast Cancer</td>
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<td>FB-10, NFI1114, NSABP FB-10, TrialTroveID-216534</td>
<td>HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV</td>
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<td>ado-trastuzumab emtansine + neratinib</td>
<td>United States</td>
<td>OH, PA, RI, WV</td>
<td>Diana Gosik [800-270-3165; <a href="mailto:diana.gosik@nsabp.org">diana.gosik@nsabp.org</a>]</td>
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<tr>
<td>NCT02547961</td>
<td>Chimeric Antigen Receptor-Modified T Cells for HER-2 Positive Recurrent and Metastatic Breast Cancer</td>
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<td>A Clinical Research of CAR T Cells Targeting HER2 Positive Cancer</td>
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ERBB2 amplification (continued)

NCT02403271
A Multi-Center Study of the Bruton’s Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination With MEDI4736, in Subjects With Relapsed or Refractory Solid Tumors.

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 positive

**Other identifiers:** 00061881, 2015-0076, PCYC-1135-CA, TrialTroveID-220168

**Population segments:** Adenocarcinoma, HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

**Phase:** I/II

**Therapy:** durvalumab + ibrutinib

**Country:** United States

**US States:** AL, AZ, CA, FL, IL, NJ, TN, TX

**US Contact:** Molly Mallough [408-215-3743; mmallough@pcyc.com]

NCT02423902
A Single-arm, Open-label Study of Ad-RTS-hIL-12 + Veledimex Following First- or Second-Line Standard Treatment in Subjects With Locally Advanced or Metastatic Breast Cancer

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 positive

**Other identifiers:** 15-024, ATI001-203, TrialTroveID-252970

**Population segments:** HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

**Phase:** I/II

**Therapy:** INXN-2001/1001

**Country:** United States

**US State:** NY

**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

No NCT ID - see other identifier(s)
Safety and Tolerability of Lapatinib in Combination with Vinorelbine (N) and Capecitabine (C) as Second Line Treatment in Patients with Her2 Positive Metastatic Breast Cancer (MBC)

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 positive

**Other identifier:** TrialTroveID-136450

**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

**Phase:** I/II

**Therapy:** lapatinib + chemotherapy

**Country:** Italy
ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
A prospective, multicentre, open-label, randomized, uncontrolled, phase 1/2 study to evaluate efficacy and safety of masitinib in combination with gemcitabine or carboplatin or capecitabine in patients with a metastatic or locally advanced breast cancer (all hormonal status tumor except triple negative tumor) and who relapsed after a first line chemotherapy.

Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: AB10005, EudraCT Number: 2010-022646-24, REec-2015-1494, TrialTroveID-203366

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER positive/negative, PR positive/negative

Phase: I/II

Therapy: masitinib + chemotherapy

Countries: France, Spain

NCT02285179
Phase I/prospective randomized phase II trial Of the Safety and Efficacy of tamoxifen in combination with the Isoform selective PI3K inhibitor GDC-0032 compared with tamoxifen alone in hormone receptor positive, HER2 negative, metastatic breast cancer patients with prior exposure to endocrine treatment (POSEIDON trial)

Cancer type: Breast Cancer
Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2013-003947-51, IRAS ID: 139349, M14POS, NL49184.031.14, POSEIDON trial, REec-2016-2238, TrialTroveID-220300, UKCRN ID: 18165

Population segments: HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER positive and/or PR positive

Phase: I/II

Therapies: tamoxifen, taselisib + tamoxifen

Countries: Netherlands, Spain, United Kingdom

NCT01816035
Thrombokinetic Studies of Ado-trastuzumab Emtansine

Cancer type: Breast Cancer
Variant class: ERBB2 amplification

Other identifiers: 7900, NCI-2013-00552, TrialTroveID-183712

Population segments: First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: ado-trastuzumab emtansine

Country: United States

US State: WA

US Contact: Vijayakrishna Gadi [206-288-2222]

DISCLAIMER: The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2016.09(002).
### ERBB2 amplification (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Other identifiers</th>
<th>Population segments</th>
<th>Phase</th>
<th>Therapy</th>
<th>Country</th>
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</thead>
</table>
| **NCT02167854**  
A Phase I, Open-Label Study Evaluating the Safety and Tolerability of LJM716, BYL719 and Trastuzumab in Patients With Metastatic HER2+ Breast Cancer.  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** ALS1004AST1306, CTR20150568, TrialTroveID-267371  
**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV  
**Phase:** I  
**Therapy:** alitinib + chemotherapy  
**Country:** China | | | | | |
| **NCT02512237**  
A Phase I, Multicenter, Open-label, Multiple Dose-escalation Study of ARX788, Intravenously Administered as a Single Agent in Subjects With Advanced Breast Cancer With Multiple Levels of HER2 Expression  
**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification  
**Other identifiers:** 14-057, TrialTroveID-211253  
**Population segments:** First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV  
**Other inclusion criteria:** PIK3CA wild type  
**Phase:** I  
**Therapy:** alpelisib + LJM-716 + trastuzumab  
**Country:** United States  
**US State:** NY  
**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts. | | | | | |
| **ONC16-0155**  
**www.oncologica.com**  
Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report. | | | | | |

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### NCT01300962
LCCC 1024: A Four Part, Phase I Dose-Escalation Study of the Combinations of Concurrent BKM120 and Capecitabine, or Concurrent BYL719 and Capecitabine, or Concurrent BKM120 and Capecitabine and Trastuzumab, or Concurrent BKM120 and Capecitabine and Lapatinib in Patients With Metastatic Breast Cancer

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** 00030313, 11-0060, LCCC 1024, LCCC1024, NCI-2013-00951, TrialTroveID-142831  
**Population segments:** HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV  
**Phase:** I  
**Therapies:** buparlisib + lapatinib + chemotherapy, buparlisib + trastuzumab + chemotherapy  
**Country:** United States  
**US State:** NC  
**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

---

### NCT02060253
A Phase I Clinical Trial of Ganetespib (Heat Shock Protein 90 Inhibitor) in Combination With Paclitaxel, Trastuzumab and Pertuzumab in Human Epidermal Growth Factor Receptor-2 Positive (HER2+) Metastatic Breast Cancer

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** 13-168, NCI-2014-00177, NYU S12-03732, TrialTroveID-202705  
**Population segments:** First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV  
**Phase:** I  
**Therapy:** ganetespib + pertuzumab + trastuzumab + chemotherapy  
**Country:** United States  
**US State:** NY  
**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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### NCT01875666
Defining the HER2 Positive (+) Breast Cancer Kinome Response to Trastuzumab, Pertuzumab, Combination Trastuzumab +Pertuzumab, or Combination Trastuzumab + Lapatinib

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** 13-401, CLAP016AUS33T, LAP200136, LCCC 1214, LCCC1214, ML28342, TrialTroveID-188436  
**Population segments:** HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III, Stage IV  
**Phase:** I  
**Therapies:** lapatinib + trastuzumab, pertuzumab, pertuzumab + trastuzumab, trastuzumab  
**Country:** United States  
**US States:** AL, IN, MA, NC, TX  
**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.
## ERBB2 amplification (continued)

### NCT02576548
A Phase I Multicenter, Open-label, Dose-escalation, and Dose-expansion Study to Evaluate the Safety, Pharmacokinetics, Immunogenicity, and Antitumor Activity of MEDI4276 in Subjects With Select HER2-expressing Advanced Solid Tumors

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** D5760C00001, NCI-2016-00412, TrialTroveID-266157

**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

**Other inclusion criteria:** ER positive/negative, PR positive/negative

**Phase:** I  
**Therapy:** MEDI-4276  
**Country:** United States  
**US States:** CA, FL, IN, NC, TN  
**US Contact:** AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

### NCT02500199
A Two-part Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Pyrotinib in Patients With HER2 Positive Solid Tumors Who Failed Prior HER2 Targeted Therapy

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** SHRUS 1001, TrialTroveID-261429

**Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

**Phase:** I  
**Therapy:** pyrotinib  
**Country:** United States  
**US State:** TX  
**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

### No NCT ID - see other identifier(s)
Feasibility study of a short Trastuzumab infusion in patients with breast cancer

**Cancer type:** Breast Cancer  
**Variant class:** ERBB2 amplification

**Other identifiers:** TrialTroveID-262799, UMIN000018294

**Population segments:** First line, HER2 positive, Stage I, Stage II, Stage III

**Phase:** I  
**Therapy:** trastuzumab  
**Country:** Japan

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**ONC16-:** 0155  
www.oncologica.com

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<th>NCT02605915</th>
<th>Other identifiers: EudraCT Number: 2015-002113-29, GO29831, NCI-2015-02225, TrialTroveID-268036</th>
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<tr>
<td><strong>A Phase Ib, Open-Label, Two-Arm Study Evaluating The Safety And Pharmacokinetics of Atezolizumab (Anti-Pd-L1 Antibody) in Combination With Trastuzumab Emtansine or With Trastuzumab And Pertuzumab in Patients With Her2 Positive Breast Cancer</strong></td>
<td><strong>Population segments:</strong> Adjuvant, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III, Stage IV</td>
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<tr>
<td><strong>Cancer type:</strong> Breast Cancer</td>
<td><strong>Phase:</strong> I</td>
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<td><strong>Variant class:</strong> ERBB2 positive</td>
<td><strong>Therapies:</strong> ado-trastuzumab emtansine + atezolizumab, ado-trastuzumab emtansine + atezolizumab + pertuzumab + trastuzumab + chemotherapy, atezolizumab + pertuzumab + trastuzumab, atezolizumab + pertuzumab + trastuzumab + chemotherapy</td>
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<td><strong>Country:</strong> United States</td>
<td><strong>US States:</strong> OH, TN</td>
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<tr>
<td><strong>US Contact:</strong> Hoffmann-La Roche Clinical Trials - Reference Study ID Number: GO29831 [888-662-6728; <a href="mailto:global.rochegenentechtrials@roche.com">global.rochegenentechtrials@roche.com</a>]</td>
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<th>Other identifiers: 8843, Mod13_STU 042013-042, NCI-2014-00821, SCCC 05113, STU 042013-042, TrialTroveID-196691</th>
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<tbody>
<tr>
<td><strong>Phase IB Study of PD-032991 in Combination with T-DM1 in the Treatment of Patients with Advanced HER2 (Human Epidermal Growth Factor Receptor 2)-Positive Breast Cancer</strong></td>
<td><strong>Population segments:</strong> HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
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<tr>
<td><strong>Cancer type:</strong> Breast Cancer</td>
<td><strong>Phase:</strong> I</td>
</tr>
<tr>
<td><strong>Variant class:</strong> ERBB2 positive</td>
<td><strong>Therapy:</strong> ado-trastuzumab emtansine + palbociclib</td>
</tr>
<tr>
<td><strong>Country:</strong> United States</td>
<td><strong>US State:</strong> TX</td>
</tr>
<tr>
<td><strong>US Contact:</strong> Dr. Arthur Frankel [214-648-4180; <a href="mailto:Arthur.Frankel@UTSouthwestern.edu">Arthur.Frankel@UTSouthwestern.edu</a>]</td>
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</tr>
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</table>
**ERBB2 amplification (continued)**

**NCT01920061**
A Phase Ib Open-Label Three-Arm Multi-Center Study To Assess The Safety And Tolerability Of PF-05212384 (pi3k/Mtor Inhibitor) In Combination With Other Anti-Tumor Agents

Cancer type: Breast Cancer  
Variant class: ERBB2 positive


Population segments: EGFR, First line, HER2 negative, HER2 positive, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I  
Therapy: dacomitinib + gedatolisib  
Countries: Canada, Italy, Spain, United Kingdom, United States  
US States: CA, CO, MA, MI, PA, SC  
US Contact: Pfizer CT.gov Call Center [800-718-1021]

**NCT02649686**
A Phase Ib Pharmacodynamic Study of Durvalumab (MEDI4736) in Patients With HER-2 Positive Metastatic Breast Cancer (MBC) Receiving Trastuzumab

Cancer type: Breast Cancer  
Variant class: ERBB2 positive

Other identifiers: I229, TrialTriovet-ID-271035

Population segments: Adjuvant, HER2 positive, Neoadjuvant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I  
Therapy: durvalumab + trastuzumab  
Country: Canada

**NCT02286219**
Phase 1, Multiple Ascending Dose Study of Anti-HER2 FCAB FS102 in HER2 Positive Solid Tumors

Cancer type: Breast Cancer  
Variant class: ERBB2 positive

Other identifiers: 2014-1221, 20142312, CA014-001, FS10214100, NCI-2015-00318, TrialTriovet-ID-220332

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I  
Therapy: FS-102  
Country: United States  
US States: DC, TN, TX, WA  
US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.
## ERBB2 amplification (continued)

### NCT02014909
- **Part I and Part II A Phase I Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of KTN3379 in Adult Subjects With Advanced Tumors Alone or With Chemotherapy**
- **Cancer type:** Breast Cancer
- **Variant class:** ERBB2 positive
- **Other identifiers:** KTN3379-CL-001, TrialTroveID-199352
- **Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage II, Stage III, Stage IV
- **Phase:** I
- **Therapy:** KTN-3379 + trastuzumab
- **Country:** United States
- **US States:** CO, CT, PA, TN
- **US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

### No NCT ID - see other identifier(s)
- **Phase I trial of S-1 plus Lapatinib in patients with HER-2 positive metastatic breast cancer**
- **Cancer type:** Breast Cancer
- **Variant class:** ERBB2 positive
- **Other identifiers:** TrialTroveID-152867, UMIN000004921
- **Population segments:** HER2 positive, Line of therapy N/A, Stage IV
- **Phase:** I
- **Therapy:** lapatinib + chemotherapy
- **Country:** Japan

### NCT02361112
- **A Phase I Study of Pyrotinib In Combination with Capecitabine In Patients With HER2 Positive Metastatic Breast Cancer**
- **Cancer type:** Breast Cancer
- **Variant class:** ERBB2 positive
- **Other identifiers:** BLTN-Ic, TrialTroveID-252048
- **Population segments:** HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV
- **Phase:** I
- **Therapy:** pyrotinib + chemotherapy
- **Country:** China

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**ONC16:- 0155**

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### ERBB2 amplification (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Other identifiers</th>
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<tr>
<td>NCT01969643</td>
<td>1311013056, 14-013, 14-306, 20131069, BRE 225 IST, NCI-2013-02245, SGNLVA-001, TrialTroveID-185934, UW 13038</td>
<td>HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV, Triple receptor negative</td>
<td>I</td>
<td>SGN-LIV1A + trastuzumab</td>
<td>United States</td>
<td>AL, CA, CT, IN, MA, MI, MN, NY, TN, WA</td>
<td>Seattle Genetics [866-333-7436; <a href="mailto:clinicaltrials@seagen.com">clinicaltrials@seagen.com</a>]</td>
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<tr>
<td>NCT02562378</td>
<td>Medopp038, TrialTroveID-265364</td>
<td>HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
<td>I</td>
<td>trastuzumab + chemotherapy</td>
<td>Spain</td>
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</tbody>
</table>
### NCT02675829

A Phase II Trial of Ado-Trastuzumab Emtansine for Patients With HER2 Amplified or Mutant Cancers

**Other identifiers:** 15-335, basket, TrialTroveID-256389

**Population segments:** First line, Stage III, Stage IV

**Phase:** II

**Therapy:** ado-trastuzumab emtansine

**Country:** United States

**US State:** NY

**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

**Cancer type:** Unspecified Cancer

**Variant class:** ERBB2 amplification

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### NCT02029001

A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients With Progressive Locally-advanced or Metastatic Solid Tumors MOST: My own specific treatment

**Other identifiers:** ET12-081, EudraCT number: 2012-004510-34, MOST, ProfiLER, TrialTroveID-200294

**Population segments:** Maintenance/Consolidation, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

**Phase:** II

**Therapy:** lapatinib

**Country:** France

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ERBB2 amplification

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### NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study

**Other identifiers:** Pro00014171, TAPUR, TrialTroveID-273941

**Population segments:** (N/A), Diffuse large B-cell lymphoma (DLBCL), Second line or greater/Refractory/Relapsed, Stage III, Stage IV

**Phase:** II

**Therapy:** pertuzumab + trastuzumab

**Country:** United States

**US States:** MI, NC

**US Contact:** Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

**Cancer type:** Unspecified Solid Tumor

**Variant class:** ERBB2 amplification

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ERBB2 amplification (continued)

NCT01935843
Clinical Study of Chimeric HER-2 Antigen Receptor-modified T Cells in Chemotherapy Refractory HER-2 Advanced Solid Tumors.

Cancer type: Unspecified Solid Tumor
Variant class: ERBB2 positive

Other identifiers: CHN-PLAGH-BT-009, TrialTroveID-193409
Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: I/II
Therapy: CART-HER-2
Country: China

NCT02583542
A Phase Ib/Ila Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers.

Cancer type: Unspecified Solid Tumor
Variant class: ERBB2 aberration

Other identifiers: 009896QM, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcmek, TrialTroveID-265019, UKCRN ID:18725
Population segments: EGFR, FGFR, HER2 negative, HER2 positive, KRAS, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative
Phase: I/II
Therapy: AZD-2014 + selumetinib
Country: United Kingdom

No NCT ID - see other identifier(s)
Phase I Clinical Study With Advanced Solid Tumors KBP-5209 Treatment

Cancer type: Unspecified Solid Tumor
Variant class: ERBB2 amplification

Other identifiers: 5209-CPK-1002, CTR20150792, TrialTroveID-269399
Population segments: EGFR, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: I
Therapy: pirotinib
Country: China

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**ERBB2 amplification (continued)**

**NCT01971515**  
A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects With Advanced Malignancies  
**Cancer type:** Unspecified Solid Tumor  
**Variant class:** ERBB2 aberration  
**Other identifiers:** 2013-0525, CHRMS 14-081, EMR100018-001, NCI-2013-02370, TrialTroveID-196334  
**Population segments:** Aggressive, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV  
**Phase:** I  
**Therapy:** MSC-2363318A  
**Country:** United States  
**US States:** CA, MI, TX, VT  
**US Contact:** US Medical Information [888-275-7376]

**FGFR4 amplification**

**NCT02052778**  
A Dose-Finding Phase I Study of TAS-120 in Patients With Advanced Solid Tumors with or without Fibroblast Growth Factor/Receptor (FGF/FGFR)-Related Abnormalities Followed By a Phase II Study in Patients With Advanced Solid Tumors or Multiple Myeloma with FGF/FGFR-Related Abnormalities  
**Cancer type:** Breast Cancer  
**Variant class:** FGFR amplification  
**Other identifiers:** 14-135, 2014-0069, EudraCT Number: 2013-004810-16, TPU-TAS-120-101, TrialTroveID-201986  
**Population segments:** FGFR, Second line or greater/Refractory/Relapsed, Stage IV  
**Phase:** I/II  
**Therapy:** TAS-120  
**Countries:** Australia, France, Spain, United Kingdom, United States  
**US States:** MA, TX  
**US Contact:** Taiho Pharma USA, Inc. - Dr. Robert Winkler [855-598-8259; rwinkler@taihooncology.com]

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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**FGFR4 amplification (continued)**

**NCT01703481**

A Phase I Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of JNJ-42756493, a Pan-Fibroblast Growth Factor Receptor (FGFR) Tyrosine Kinase Inhibitor, in Subjects with Advanced or Refractory Solid Tumors or Lymphoma

Cancer type: Breast Cancer

Variant class: FGFR amplification

Other identifiers: 2013-0551, 42756493EDI1001, CR100845, DFCI ID: 14-170, EudraCT Number: 2012-000697-34, J & J PanFGFR 42756493DEI1001, Janssen 42756493EDI1001, RECF2147, STU 072013-039, TrialTroveID-174615

Population segments: Aggressive, Classical, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV

Other inclusion criteria: KRAS wild type

Phase: I

Therapy: erdafitinib

Countries: France, Spain, United States

US States: AL, AZ, CA, CO, FL, GA, IL, IN, MA, MI, MO, NC, NJ, NM, TN, TX, VA

US Contact: Janssen Research & Development, LLC [JNJ.CT@syllogent.com]

**NCT02272998**

Phase II study of ponatinib for advanced cancers with genomic alterations in fibroblastic growth factor receptor (FGFR) and other genomic targets (KIT, PDGFRa, RET FLT3, ABL1)

Cancer type: Unspecified Solid Tumor

Variant class: FGFR amplification

Other identifiers: NCI-2014-01499, OSU-14078, TrialTroveID-219466

Population segments: Advanced, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: ponatinib

Country: United States

US States: MI, OH

US Contact: The Ohio State University Comprehensive Cancer Center [800-293-5066]

**DISCLAIMER:** The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2016.09(002).
NCT02160041
Modular Phase II Study to Link Targeted Therapy to Patients With Pathway Activated Tumors: Module 6 - BGJ398 for Patients With Tumors With FGFR Genetic Alterations
Cancer type: Unspecified Solid Tumor
Variant class: FGFR aberration
Other identifiers: 00058827, 15.0136(UofL), 2014-0569, CBGJ398XUS04, "CBGJ398XUS04, Signature", CTMS# 14-2025, F15083, TrialTroveID-210608
Population segments: Advanced, Second line or greater/Refractory/Relapsed, Stage III, Stage IV
Phase: II
Therapy: infigratinib
Country: United States
US States: AL, CA, CO, GA, IL, IN, KY, MA, MD, MI, MO, MT, NC, ND, NH, NJ, NM, OH, OR, PA, RI, SD, TN, TX, UT, VA, WA
US Contact: Novartis Pharmaceuticals [888-669-6682]

NCT01752920
A Phase I/II Study of ARQ 087 in Adult Subjects With Advanced Solid Tumors With FGFR Genetic Alterations, Including Intrahepatic Cholangiocarcinoma With FGFR2 Gene Fusion
Cancer type: Unspecified Solid Tumor
Variant class: FGFR amplification
Other identifiers: ARQ 087-101, NCI-2013-00121, TrialTroveID-179037
Population segments: Advanced, Locally advanced, Metastatic, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Unresectable
Phase: I/II
Therapy: ARQ-087
Countries: Italy, United States
US States: GA, NY, PA, TX, WA
US Contact: ArQule, Inc. [781-994-0300; ClinicalTrials@arqule.com]

NCT02583542
A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers.
Cancer type: Unspecified Solid Tumor
Variant class: FGFR aberration
Other identifiers: 009896QM, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcmek, TrialTroveID-265019, UKCRN ID:18725
Population segments: EGFR, FGFR, HER2 negative, HER2 positive, KRAS, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative
Phase: I/II
Therapy: AZD-2014 + selumetinib
Country: United Kingdom

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

DISCLAIMER: The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2016.09(002).
### FGFR4 amplification (continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Title</th>
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<th>Variant class</th>
<th>Other identifiers</th>
<th>Population segments</th>
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<th>Therapy</th>
<th>Countries</th>
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<tr>
<td>NCT02608125</td>
<td>A Phase I Open-Label, Multicenter, Dose-Escalation Study of PRN1371, a FGFR I-IV Kinase Inhibitor, in Adult Patients With Advanced Solid Tumors, Followed by an Expansion Cohort in Patients With FGFR I, II, III, or IV Genetic Alterations</td>
<td>Unspecified Solid Tumor</td>
<td>FGFR4 aberration</td>
<td>PRN1371-001, TrialTroveID-268202</td>
<td>Second line or greater/Refractory/Relapsed, Stage III, Stage IV</td>
<td>I</td>
<td>PRN-1371</td>
<td>Spain, United States</td>
<td>TX</td>
<td>The University of Texas MD Anderson Cancer Center Recruiting [650-416-7700]</td>
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<tr>
<td>NCT01697605</td>
<td>A Phase I Study of Oral BGJ398 in Asian Patients with Advanced Solid Tumor Having Alterations of the FGF-R Pathway</td>
<td>Unspecified Solid Tumor</td>
<td>FGFR aberration</td>
<td>CBGJ398X1101, CTR20140515, JapicCTI-132280, TrialTroveID-175337</td>
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<td>infigratinib</td>
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### Appendix: Evidence Summary by Variant Class

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

#### ERBB2 amplification

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<th>Variant Class</th>
<th>Evidence Items</th>
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<td>ERBB2 positive</td>
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<td>ERBB2 amplification</td>
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#### FGFR4 amplification

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<td>FGFR aberration</td>
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<tr>
<td>FGFR4 aberration</td>
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<tr>
<td>FGFR4 amplification</td>
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<td>FGFR amplification</td>
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<tr>
<td>FGFR4 amplification</td>
<td>0</td>
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</table>
Report Signed by

Report Checked by

Clinical Scientist ☑
Pathologist ☐
BMS (Senior) ☐

BMS ☑
6. Liability

6.1 Oncologica operates in compliance with international ISO15189:2012 standards and is regulated by UKAS. The Oncologica Tests have not been cleared or approved by the United States Food and Drug Administration; however, such clearance or approval is not required.

6.2 The Patient agrees that the Oncologica Test Report is intended for clinical use and interpretation by a physician who is experienced and skilled in the use and interpretation of clinical test data. The Oncologica Test Report is based on the Sample submitted by the Patient. The Oncologica Test Report should not be considered or its contents applied to any other patient or any other sample. Oncologica does not update an Oncologica Test Report once it has been sent.

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6.5 Subject to paragraph 6.10, Oncologica shall have no liability for any use made of the information provided in the Oncologica Test Report, including but not limited to any report prepared by Oncologica summarising the results of the Oncologica Tests, any advice supplied by Oncologica, any decisions taken, or for any costs incurred by Patient and/or the Patient’s physician and/or the Agent in consequence of such use, advice or decisions. The Oncologica Test and/or the Oncologica Test Report is not a substitute for the Patient’s physician’s professional judgment. The use of the information provided in the Oncologica Test Report is provided as a tool for the ordering physician’s use in determining the appropriate treatment for the Patient. The decision as to what course of treatment and the appropriate use of the information provided by the Oncologica Test Report is solely that of the Patient’s physician.

6.6 Oncologica does not warrant or represent or guarantee that the Oncologica Tests will identify an actionable genetic alteration that is linked to anti-cancer targeted therapies. Although the Oncologica Tests are comprehensive, in a proportion of Patients, the Oncologica Test result may not identify any actionable mutations for a patient’s cancer. In the event that no actionable alteration in the Sample is identified by the Oncologica Test, then the Patient is still under full obligation to pay the Charges and no refund is available to the Patient and/or Agent.

6.7 The Oncologica Test identifies genomic actionable alterations found in the submitted Sample that are linked to anti-cancer targeted agents. Also note that this test only examines tumour, and not normal tissue from the patient, and therefore cannot distinguish between somatic and germline (i.e., heritable) alterations.

6.8 Subject to Clause 6.8, Oncologica shall not be liable to the Patient whether in contract, tort (including negligence and breach of statutory duty), or otherwise for any:

(a) Error or defect in the Oncologica Test Report as a result of any inaccurate or incomplete information supplied by the Patient;

(b) Loss of data or materials, including the Sample and/or the Report and including any loss arising as a result of the acts or omissions of a courier;

(c) Indirect or consequential loss arising whether or not advised of the possibility of the same.

6.9 Subject to the provisions of this Clause 6, Oncologica’s total liability to the Patient in respect of all losses arising under or in connection with the Contract, whether in contract, tort (including negligence and breach of statutory duty), or otherwise, shall in no circumstances exceed the Charges paid for the Test that is the subject of the claim.

6.10 Nothing in the Contract limits or excludes the liability of Oncologica for breach of its obligations under section 12 of the Sale of Goods Act 1979 and/or section 2 of the Supply of Goods and Services Act 1982; death or personal injury resulting from negligence; or fraud or fraudulent misrepresentation.

6.11 If the Patient is a consumer (and not a business), the Patient expressly acknowledges and agrees that the Test is supplied to the Patient’s specification and therefore there is no right to cancel the Test following acceptance under Clause 2.2. If the Patient is a consumer, then notwithstanding any other provisions of the Contract, none of the Patient’s consumer statutory rights are affected.