

**HER2 POSITIVE BREAST CANCER TRIALS:**

1. **Metastatic HER2 Positive**

**HR POSITIVE BREAST CANCER TRIALS:**

1. **Metastatic HR Positive (1<sup>st</sup> Line)**
2. **Metastatic HR Positive (>1<sup>st</sup> Line)**

**IMMUNOTHERAPY:**

1. **Metastatic**
2. **Local Recurrence**

**GENOMICALLY TARGETED OR ENRICHED TRIALS:**

1. **FGFR1/2 Amplification**
2. **PIK3CA mutation/PTEN loss**
3. **HER2 mutations**
4. **TP53 Wild Type**

**TRIPLE NEGATIVE BREAST CANCER:**

1. **First line Metastatic TNBC**
2. **Second Line Metastatic TNBC**
3. **≥3 Lines for mTNBC**

**BREAST CANCER WITH BRAIN METASTASIS:**

1. **HER2+ (BMO)**
2. **HER2- (BMO)**
3. **LMD (BMO)**
4. **Active CNS Radiation Oncology Trials Enrolling Breast Patients**

**BRCA BREAST CANCER TRIALS:**

1. **Metastatic**

**INFLAMMATORY BREAST CANCER:**

1. **HER2-/ER+, HER2+/Any HR**
2. **IBC with Metastasis**

**ALL SUBTYPES:**

1. **Post-Mortem Tissue Collection**

**HER2 POSITIVE BREAST CANCER TRIALS:**

**1. Metastatic HER2 Positive**

**First Line:**

**a. 2020-0260** Phase 1b/II of Copanlisib in Combination with Trastuzumab and Pertuzumab after Induction Treatment of HER2 Positive (HER2+) Metastatic Breast Cancer (MBC) with PIK3CA Mutation or PTEN Mutation

PI: Senthil Damodaran

SM: Keena Woods

**b. NRG-BR004:** A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First Line HER2-Positive Metastatic Breast Cancer **\*ON HOLD\***

PI: Vicente Valero

RN: Danielle Alanis

**Second Line:**

**Third Line:**

**a. 2020-0862:** A Single Arm, Open Label Phase 2 Study of Tucatinib in Combination with Trastuzumab Deruxtecan in Subjects with Previously Treated Unresectable Locally Advanced or Metastatic HER2+ Breast Cancer

PI: Rashmi Murthy

RN: Jennifer Childress

**b. 2018-0486** A Randomized, Phase II Study Comparing Trastuzumab and Vinorelbine in Combination with Avelumab or Avelumab and Utomilumab (41BB/CD137 Agonist) in Patients with HER2-positive Metastatic Breast Cancer who have Progressed on prior Trastuzumab and Pertuzumab: The “Aviator” Study

PI: Rashmi Murthy

RN: Danielle Alanis

**Any Line:**

**ICT (Any Line)**

**a. 2016-0532** Phase 1 Trial of ZW25 in Patients with Locally Advanced (Unresectable) and/or Metastatic HER2-Expressing Cancers (Note: Chemo combos available with Capecitabine, Vinorelbine, and Tucatinib/Capecitabine; HER2 3+ or HER2 2+/FISH positive; must have received prior therapy with Trastuzumab, Pertuzumab, and T-DM1) (\*Phase 1)

PI: Funda Meric-Bernstam

SM: Kathleen Kong

**b. 2016-0430** Phase 1 Study of the Pan-ERBB Inhibitor Neratinib Given in Combination with Everolimus, Palbociclib or Trametinib in Advanced Cancer Subjects with EGFR Mutation/Amplification, HER2 Mutation/Amplification or HER3/4 Mutation ( \*Phase 1)

PI: Sarina Piha-Paul

SM: Qianqian Wang

- c. [2018-0318](#) A Phase I-II, First-in-Human Study of A166 in Patients with Locally Advanced/Metastatic Solid Tumors which are Human Epidermal Growth Factor Receptor 2(HER2)-Positive who did not Respond or Stopped Responding to Approved Therapies and Patients with HER2 Positive (by ISH or NGS) or Low Expressing (by IHC) Solid Tumors who did not Respond or Stopped Responding to Approved Therapies (\*Phase 1) **\*ON HOLD\***  
PI: Jordi Rodon  
SM: Diana Lopez
- d. [2017-1009](#): A Phase 1, Open-Label, Dose Escalation Study of the Safety and Pharmacokinetics of BTRC4017A administered Intravenously in Patients with Locally Advanced or Metastatic HER2-expressing cancers (Note: enrolling HR+ and TNBC patients) (\*Phase1)  
PI: Timothy Yap  
SM: Ileana Gutierrez
- e. [2020-0326](#): A Phase 1/1b Open-Label, Dose Escalation and Expansion Study of SBT6050 Alone and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors Expressing HER2  
PI: Sarina Piha-Paul  
SM: Meng Gao
- f. [2019-1232](#): A Phase I, Open Label, Dose Escalation Study of ACE1702 Cell Immunotherapy in Subjects with Advanced or Metastatic HER2- expressing Solid Tumors  
PI: Sarina Piha-Paul  
SM: Xueyao Fu
- g. [2019-1111](#): Phase 1/2 Study of BDC-1001 as a Single Agent and in Combination with Pembrolizumab in Patients with Advanced HER2-Expressing Solid Tumors  
PI: Ecaterina Dumbrava  
SM: Jeane Painter
- h. [2020-0675](#): A Phase 1/2, Open-Label, Multicenter, Non-Randomized, Safety and Activity Study of HER2-Targeted Dual Switch CAR-T Cells (BPX-603) in Subjects with Previously Treated Advanced HER2-Positive Solid Tumors  
PI: Ecaterina Dumbrava  
SM: Jeane Painter
- i. [2019-1175](#): A Phase 1/2, Open-Label, Two-part, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics and Antitumor Activity of BDTX-189, an Inhibitor of Allosteric ErbB Mutations, in Patients with Advanced Solid Malignancies  
PI: Jordi Rodon  
SM: Uyen Vu

**j. [2021-0298](#):** A Phase 1b/2, 2-part Open-label Study to Assess the Safety and Antitumor Activity of Zanidatamab in Combination with ALX148 in Advanced HER2-expressing Cancer (**\*Phase1**)

PI: Funda Meric-Bernstam

SM: Kathleen Kong

**k. [2020-1161](#):** A Phase I/II Trial Investigating Safety and Efficacy of Autologous TACT Cells Targeting HER2 in Relapsed or Refractory Solid Tumors (TACTI-2)

PI: Ecaterina Dumbrava

SM: Jeane Painter

**HR POSITIVE BREAST CANCER TRIALS:**

**1. [Metastatic HR Positive \(1<sup>st</sup> Line\)](#)**

**a. [2018-0287](#):** INTERACT- INTEGRATED Evaluation of Resistance and Actionability Using Circulating Tumor DNA in HR Positive Metastatic Breast Cancers

PI: Senthil Damodaran

RN: Danielle Alanis

**b. [2020-1173](#):** EMBER: A Phase 1a/1b Study of LY3484356 Administered as Monotherapy and in Combination with Anticancer Therapies for Patients with ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

PI: Rachel Layman

RN: Heather Alonzo

**c. [2019-0999](#):** A Phase ½ Open Label, Multicenter Study to Assess the Safety, Tolerability, of Anti-Tumor Activity of Zn-C5 alone and in Combination with Palbociclib in Subjects with ER+/HER2 Negative Advanced Breast Cancer **\*ON HOLD\***

PI: Rachel Layman

RN: Danielle Alanis

**2. [Metastatic HR Positive \(>1<sup>st</sup> Line\)](#)**

**a. [2017-0918](#)** Phase 1/2A Dose Escalation and Expansion Study of PFPF 06873600 As A Single Agent and In Combination with Endocrine Therapy

PI: Timothy Yap/Rachel Layman

RN: Sandra Montez

**b. [2016-0538](#):** Phase Ib study of BYL719 (Alpelisib) in combination with androgen receptor inhibitor (enzalutamide) in patients with androgen receptor (AR)-positive and PTEN positive metastatic breast cancer

PI: Meghan Karuturi

RN: Jennifer Childress

**c. [2019-0999](#):** A Phase 1/2 Open-Label, Multicenter Study to Assess the Safety, Tolerability, of Anti-Tumor Activity of Zn-C5 Alone and in Combination with Palbociclib in Subjects with ER+/HER2 Negative Advanced Breast Cancer **\*ON HOLD\***

PI: Rachel Layman

RN: Danielle Alanis

**d. [2020-1173](#):** EMBER: A Phase 1a/1b Study of LY3484356 Administered as Monotherapy and in Combination with Anticancer Therapies for Patients with ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

PI: Rachel Layman

RN: Heather Alonzo

**e. [2021-0033](#):** Evaluation of Talazoparib, a PARP Inhibitor, in Patients with Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial

PI: Senthil Damodaran

SM: Makeba Faniel

## **IMMUNOTHERAPY**

### **1. [Metastatic](#)**

### **2. [Metastatic – IBC/TNBC](#)**

**a. [2014-0533](#)** MK-3475 (anti-PD-1) Therapy in Patients with Metastatic IBC Who Have Received Prior Chemo with Complete or Partial Response

PI: Naoto Ueno

RN: Vivian Chiv

## **GENOMICALLY TARGETED OR ENRICHED TRIALS**

### **1. [FGFR1/2 Amplification](#)**

**a. [2019-0526](#)** A Phase 2 Study of TAS-120 in Metastatic Breast Cancer Harboring Fibroblast Growth Factor Receptor (FGFR) Amplifications

PI: Senthil Damodaran

RN: Danielle Alanis

### **2. [PIK3CA Mutation/PTEN loss](#)**

### **3. [HER2 Mutations](#)**

**a. [2013-0904](#)** An Open-Label, Phase 2 Study of Neratinib in Patients with Solid Tumors with Somatic Human Epidermal Growth Factor (EGFR, HER2, HER3) mutations or EGFR Gene Amplification

PI: Sarina Piha-Paul

SM: Rabia Khan

### **4. [TP53 Wild Type](#)**

**a. [2018-0561](#)** A Phase 1b Study of ALRN-6924 in Combination with Paclitaxel in Wild-type TP53 Advanced or Metastatic Solid Tumors including Estrogen-Receptor Positive Breast Cancer

PI: Funda Meric-Bernstam

RN: Julia Moore

### **5. [ESR1 Mutations](#)**

**TRIPLE NEGATIVE BREAST CANCER**

**1. First line Metastatic TNBC**

a. [2020-1167](#): An Open-label Phase 1b Study of ORIC-101 in Combination with Anticancer Therapy in Patients with Advanced or Metastatic Solid Tumors-Part II

PI: Naoto Ueno

RN: Jennifer Childress

b. [2020-0691](#): EPIK-B3: A Phase III, Multicenter, Randomized, Double-blind, Placebo Controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719), in Combination with Nab-paclitaxel in Patients with Advanced Triple Negative Breast Cancer with Either Phosphoinositidine-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

PI: Debasish Tripathy

RN: Jennifer Childress

**2. Second Line Metastatic TNBC**

a. [2020-0691](#): EPIK-B3: A Phase III, Multicenter, Randomized, Double-blind, Placebo Controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719), in Combination with Nab-paclitaxel in Patients with Advanced Triple Negative Breast Cancer with Either Phosphoinositidine-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation

PI: Debasish Tripathy

RN: Jennifer Childress

b. [2021-0145](#): An Open-Label, Phase 1b/2 Study to Evaluate the Safety and Efficacy of Fruquintinib in Combination with Tislelizumab in Patients with Advanced Triple Negative Breast Cancer

PI: Haven Garber

RN: Alyson Clayborn

c. [2016-1096](#) A Phase I Study of OTS167P0, a MELK Inhibitor, to Evaluate Safety, Tolerability and Pharmacokinetics in Patients with Advanced Breast Cancer and Dose-Expansion Study in Patients with Triple Negative Breast Cancer and Dose-Expansion Study in Patients with Triple Negative Breast Cancer

PI: Naoto Ueno

RN: Vivian Chiv

SM: Gil Guerra

d. [2016-0538](#): Phase 1b study of BYL719 (Alpelisib) in combination with androgen receptor inhibitor (enzalutamide) in patients with androgen receptor (AR)-positive and PTEN positive metastatic breast cancer

PI: Meghan Karuturi

RN: Jennifer Childress

e. [2014-0533](#): MK-3475 (a-PD-1) Therapy in Patients with Metastatic IBC Who Have Received Prior Chemo with Complete or Partial Response

PI: Naoto Ueno

RN: Vivian Chiv

f. [2014-0640](#): A Phase 1b Study to Evaluate the Safety of Selinexor (KPT-330) in Combination with Multiple Standard Chemotherapy Agents in Patients with Advanced Malignancies

PI: Aung Naing

SM: Holly Oakley

g. [2019-0496](#): A Multi-Center, Open-Label, Phase1/1B Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Anti-Cancer Activity of Fruquintinib in Patients with Advanced Solid Tumors

PI: Arvind Dasari/Debu Tripathy

RN: Alyson Clayborn

**3. ≥3 Lines for mTNBC**

a. [2016-1096](#) A Phase I Study of OTS167P0, a MELK Inhibitor, to Evaluate Safety, Tolerability and Pharmacokinetics in Patients with Advanced Breast Cancer and Dose-Expansion Study in Patients with Triple Negative Breast Cancer and Dose-Expansion Study in Patients with Triple Negative Breast Cancer

PI: Naoto Ueno

RN: Vivian Chiv

SM: Gil Guera

b. [2016-0538](#): Phase 1b study of BYL719 (Alpelisib) in combination with androgen receptor inhibitor (enzalutamide) in patients with androgen receptor (AR)-positive and PTEN positive metastatic breast cancer

PI: Meghan Karuturi

RN: Jennifer Childress

c. [2014-0533](#): MK-3475 (a-PD-1) Therapy in Patients with Metastatic IBC Who Have Received Prior Chemo with Complete or Partial Response

PI: Naoto Ueno

RN: Vivian Chiv

d. [2014-0640](#): A Phase 1b Study to Evaluate the Safety of Selinexor (KPT-330) in Combination with Multiple Standard Chemotherapy Agents in Patients with Advanced Malignancies

PI: Aung Naing

SM: Holly Oakley

e. [2019-0496](#): A Multi-Center, Open-Label, Phase1/1B Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Anti-Cancer Activity of Fruquintinib in Patients with Advanced Solid Tumors

PI: Arvind Dasari/Debu Tripathy

RN: Alyson Clayborn

**4. Metastatic TNBC and Chest wall Metastasis**

**BREAST CANCER WITH BRAIN METASTASIS**

1. HER2+ (BMO)
2. HER2- (BMO)
3. LMD HER2+(BMO)
4. Active CNS Radiation Oncology Trials Enrolling Breast Patients  
<http://inside.mdanderson.org/departments/cns-metastases-program/research.html>

**BRCA BREAST CANCER TRIALS**

1. Metastatic
  - a. 2018-0062: Overcoming PARP Inhibitor Resistance in BRCA Germline Mutation Positive Advanced Breast Cancer  
PI: Banu Arun  
RN: Danielle Alanis

**INFLAMMATORY BREAST CANCER**

1. HER2-/ER+, HER2+/Any HR
2. IBC with Metastasis
  - a. 2014-0533 Phase 2 Anti-PD1 for MBC (including IBC) Achieved Clinical response or Stable Disease  
PI: Naoto Ueno  
RN: Vivian Chiv
  - b. 2016-0890: A Phase II Study of Triple Combination of Atezolizumab Cobemetinib plus Eribulin (ACE) or AC in Patients with Chemotherapy Resistant Metastatic Inflammatory Breast Cancer  
PI: Vicente Valero  
SM: Angela Alexander
  - c. 2016-1096: A Phase I Study of OTS167PO, a MELK Inhibitor, to Evaluate Safety, Tolerability and Pharmacokinetics in Patients with Advanced Breast Cancer and Dose-Expansion Study in Patients with Triple Negative Breast Cancer  
PI: Naoto Ueno  
RN: Vivian Chiv  
SM: Gil Guerra
  - d. A Phase Ib/II Study of Grapiprant (IK-007) and Eribulin Combination Treatment for Metastatic Inflammatory Breast Cancer (mIBC)  
PI: Naoto Ueno  
RN: Angela Marx



**ALL SUBTYPES**

**1. Post-Mortem Tissue Collection Program**

- a. PA16-0791 Post-Mortem Tissue Collection from Individuals with Metastatic Breast Cancer  
PI: Nicholas Navin/Vicente Valero

**2. ABC Registry**

- a. 2019-0993 Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD  
Anderson Cancer Center  
PI: Abbey Kaler  
SM: Makeba Faniel

PI – Primary Investigator  
RN – Registered Nurse  
SM – Study Manager  
BMO – Breast Medical Oncology  
LMD – Leptomeningeal Disease  
CNS – Central Nervous System