

**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: Samantha Trager

**b. 2017-0361** A Randomized, Open Label, Phase III Trial to Evaluate the Efficacy and Safety of Palbociclib + Anti-HER2 Therapy + Endocrine Therapy vs. Anti-HER2 Therapy + Endocrine Therapy after Induction Treatment for Hormone Receptor Positive (HR+)/HER2-Positive Metastatic Breast Cancer

PI: Rashmi Murthy (**Debu Tripathy**)

RN: Jill Schwartz-Gomez

**Second Line:**

**Third Line:**

**a. 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

**b. 2018-0600** A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Study Of DS-8201a, an Anti-HER2 Antibody Drug Conjugate Versus Treatment of Investigator’s Choice for HER2-Positive, Unresectable and/or Metastatic Breast Cancer Subjects Pretreated with Prior Standard of Care HER2 Therapies, Including T-DM1

PI: Rashmi Murthy

SM: Samantha Zarda

**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: Allows enrollment of HER2+ and HER2 low expression (IHC 2+ any line and 1-3+ IHC that had 3 lines of chemo or less; FISH negative will need biopsy to confirm)**)(\*Phase 1)

PI: Funda Meric-Bernstam

SM: Kathleen Kong

**b. 2018-0667** A Phase 1b, Open-Label, Dose Escalation Study of PRS-343 in Combination with Atezolizumab in Patients with Specific HER2-Positive Advanced or Metastatic Solid Tumors (**\*Phase 1**)

PI: Sarina Piha-Paul

SM: Wendy Xiong

- c. [2017-0297](#)** Phase 1, Open-Label, Dose Escalation Study of PRS-343 in Patients with HER2-Positive Advanced or Metastatic Solid Tumors (**\*Phase 1**)  
 PI: Sarina Piha-Paul  
 SM: Thao Nguyen
- d. [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
- e. [2017-0539](#)** A Phase 1 Dose Escalation Study Evaluating the Safety and Tolerability of PF-06804103 in Patients with Human Epidermal Growth Factor Receptor 2 (HER2) Positive Solid Tumors (**\*Phase 1**)  
 PI: Funda Meric-Bernstam  
 RN: Julia Moore
- f. [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**)  
 PI: Jordi Rodon  
 SM: Diana Lopez
- g. [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**) (**\*Phase 1**)  
 PI: Timothy Yap  
 SM: Ileana Gutierrez

**HR POSITIVE BREAST CANCER TRIALS:****1. [Metastatic HR Positive \(1st Line\)](#)**

- a. [2017-0071](#)**: Phase I/II Safety and Efficacy of Autophagy Inhibition with Hydroxychloroquine to Augment the Antiproliferative and Biological Effects of Pre-Operative Palbociclib plus Letrozole for Estrogen Receptor-Positive and HER2-Negative Breast Cancer  
 PI: Debu Tripathy  
 RN: Christine Samuel
- b. [2018-0287](#)**: INTERACT- INTEGRATED Evaluation of Resistance and Actionability Using Circulating Tumor DNA in HR Positive Metastatic Breast Cancers  
 PI: Senthil Damodaran  
 SM: Samantha Zarda

**3. Metastatic HR Positive (>1st Line)**

a. [2017-0499](#): RACHEL1: A Phase 1 Radiation and Checkpoint Blockade Trial in Patients with Metastatic Hormone Receptor Positive Her2 Negative Breast Cancer

PI: Jennifer Litton

RN: Jill Schwartz-Gomez

b. [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

c. [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

SM: Gil Guera

d. [2018-0828](#): A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Trial of DS-8201A, An Anti-HER2 Antibody Drug Conjugate (ADC), Versus Treatment of Physician's Choice for HR-Positive, HER2-Low Expressing, Unresectable and/or Metastatic Breast Cancer Subjects

PI: Naoto Ueno

RN: Christine Samuel

e. [2019-0267](#): A Phase II, Multicenter, Open-Label, Three-Cohort, Non-Comparative Study to Assess the Efficacy and Safety of Alpelisib Plus Fulvestrant or Letrozole in Patients with PIK3CA Mutant, Hormone Receptor (HR) Positive, HER2-Negative Advanced Breast Cancer (ABC), Who have Progressed on or after Prior Treatments.

PI: Senthil Damodaran

SM: Danielle Kwiatkowski

**IMMUNOTHERAPY**

**1. Metastatic**

a. [2017-0499](#): RACHEL1: A Phase 1 Radiation and Checkpoint Blockade Trial in Patients with Metastatic Hormone Receptor Positive Her2 Negative Breast Cancer

PI: Jennifer Litton

RN: Jill Schwartz-Gomez

b. [2017-0500](#): A Phase 1b Trial of M7824 and Eribulin in Patients with Metastatic Triple Negative Breast Cancer (TNBC)

PI: Jennifer Litton

RN: Christine Samuel

**2. Metastatic – IBC**

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: Charla Parker

**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**

- a. [2016-0212](#) A Phase 2 Dose Escalation Study of ARQ 751 in Adult Subjects with Advanced Solid Tumors with AKT1,2,3 Genetic Alterations, Activating PIK3 mutations or PTEN null, or other known actionable PTEN mutations  
PI: Shubham Pant  
SM: Rasha Alfattal

**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

**TRIPLE NEGATIVE BREAST CANCER**

**1. First line Metastatic TNBC**

- a. [2017-0500](#): A Phase 1b Trial of M7824 and Eribulin in Patients with Metastatic Triple Negative Breast Cancer (TNBC)  
PI: Jennifer Litton  
RN: Christine Samuel

**2. Second Line Metastatic TNBC**

- a. [2017-0500](#): A Phase 1b Trial of M7824 and Eribulin in Patients with Metastatic Triple Negative Breast Cancer (TNBC)  
PI: Jennifer Litton  
RN: Christine Samuel
- b. [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: Bora Lim  
RN: Charla Parker

SM: Ameena Manzoor

c. [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

d. [2018-1112](#): A Phase 2 Study of ZEN003694 in Combination with Talazoparib in Patients with Triple-Negative Breast Cancer

PI: Jennifer Litton

SM: Samantha Trager

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: Charla Parker

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. [2018-0828](#): A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Trial of DS-8201A, An Anti-HER2 Antibody Drug Conjugate (ADC), Versus Treatment of Physician's Choice for HR-Positive, HER2-Low Expressing, Unresectable and/or Metastatic Breast Cancer Subjects

PI: Naoto Ueno

RN: Christine Samuel

**3. ≥3 Lines for mTNBC**

a. [2017-0500](#): A Phase 1b Trial of M7824 and Eribulin in Patients with Metastatic Triple Negative Breast Cancer (TNBC)

PI: Jennifer Litton

RN: Christine Samuel

b. [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: Bora Lim

RN: Charla Parker

SM: Gil Guera

c. [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

d. [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: Charla Parker

e. [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

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

#### **BREAST CANCER WITH BRAIN METASTASIS**

##### **1. HER2+ (BMO)**

##### **2. HER2- (BMO)**

##### **3. LMD HER2+(BMO)**

a. [2017-0615](#): A Phase II Non-Randomized Study to Assess the Safety and Efficacy of the Combination of Tucatinib and Trastuzumab and Capecitabine for Treatment of Leptomeningeal Metastasis in Her2 Positive Breast Cancer

PI: Rashmi Murthy

RN: Christine Samuel

#### **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

SM: Samantha Trager

#### **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: Charla Parker

b. [PA16-0507](#) Monitoring of CTCs in Newly Diagnosed Metastatic Breast Cancer

PI: Naoto Ueno

SM: Anita Wood

**ALL SUBTYPES**

**1. [Post-Mortem Tissue Collection Program](#)**

a. [PA16-0791](#) Post-Mortem Tissue Collection from Individuals with Metastatic Breast Cancer

PI: Nicholas Navin/Bora Lim

PI – Primary Investigator

RN – Registered Nurse

SM – Study Manager

BMO – Breast Medical Oncology

LMD – Leptomeningeal Disease

CNS – Central Nervous System