HER2 POSITIVE BREAST CANCER TRIALS:
  1. Metastatic HER2 Positive

HR POSITIVE BREAST CANCER TRIALS:
  1. Metastatic HR Positive (1st Line)
  2. Metastatic HR Positive (>1st 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

Updated 08/13/2020
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

2. **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

3. **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 Pha-Paul
   SM: Wendy Xiong

Updated 08/13/2020
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/Amplication, HER2 Mutation/Amplication 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) (*Phase1)
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

PI: Senthil Damodaran
SM: Samantha Zarda

Updated 08/13/2020
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 Ib 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

Updated 08/13/2020
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 Al fattal

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 0TS167P0, 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

Updated 08/13/2020
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**  

**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

Updated 08/13/2020
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

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

Updated 08/13/2020