HER2 POSITIVE BREAST CANCER TRIALS:
1. Metastatic HER2 Positive

HR POSITIVE BREAST CANCER TRIALS:
1. Metastatic Postmenopausal HR Positive (1st Line)
2. Metastatic Premenopausal HR Positive (1st Line)
3. Metastatic Postmenopausal HR Positive (>1st Line)
4. Metastatic Premenopausal HR positive (>1st Line)

IMMUNOTHERAPY:
1. Metastatic
2. Local Recurrence

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**
   a. **First Line:**
      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:**
   a. **2018-0486** A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Study of DS-8201a, an Anti-HER2 Antibody Drug Conjugate Versus Ado-Trastuzumab Emtansine (T-DM1) For HER2 Positive Unresectable and/or Metastatic Breast Cancer Subjects Previously Treated with Trastuzumab and Taxane
      PI: Rashmi Murthy
      SM: Samantha Zarda

3. **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

4. **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

Updated 06/19/2020
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/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) (*Phase 1*)
   PI: Timothy Yap
   SM: Ileana Gutierrez

**HR POSITIVE BREAST CANCER TRIALS:**

1. **Metastatic Postmenopausal 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. 2017-0651: A Phase 1/2 Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK525762 in Combination with Fulvestrant in Subjects with ER+ Breast Cancer
PI: Rachel Layman
SM: Danielle Kwiatkowski

PI: Senthil Damodaran
SM: Samantha Zarda

2. Metastatic Premenopausal HR Positive (1st Line)
a. 2017-0651: A Phase 1/2 Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK525762 in Combination with Fulvestrant in Subjects with ER+ Breast Cancer
PI: Rachel Layman
SM: Danielle Kwiatkowski

3. Metastatic Postmenopausal HR Positive (>1st Line)
a. 2017-0651: A Phase 1/2 Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK525762 in Combination with Fulvestrant in Subjects with ER+ Breast Cancer
PI: Rachel Layman
SM: Danielle Kwiatkowski

b. 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

c. 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

d. 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

e. 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

Updated 06/19/2020
4. **Metastatic Premenopausal HR Positive (>1st Line)**
   a. **2017-0651**: A Phase 1/2 Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK525762 in Combination with Fulvestrant in Subjects with ER+ Breast Cancer  
      PI: Rachel Layman  
      SM: Danielle Kwiatkowski  
   b. **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

**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

**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  
SM: Gil Guera

d. **2018-1112**: A Phase 2 Study of ZEN003694 in Combination with Talazoparib in Patients with Triple-Negative Breast Cancer  
PI: Jennifer Litton  
RN: Sara Amri

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

h. **2018-1014**: Phase 1/2, Multicenter, Open-Label, Multiple Dose, First-In Human Study of U3-1402 in Subjects with HER3-Positive Metastatic Breast Cancer  
PI: Naoto Ueno  
RN: Christine Samuel

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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

Updated 06/19/2020
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
   SM: Gil Guera

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

f. **2018-1014**: Phase 1/2, Multicenter, Open-Label, Multiple Dose, First-In Human Study of U3-1402 in Subjects with HER3-Positive Metastatic Breast Cancer
   PI: Naoto Ueno
   RN: Christine Samuel

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**

Updated 06/19/2020
BRCA BREAST CANCER TRIALS

1. Metastatic

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

Updated 06/19/2020