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
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: Danielle Kwiatkowski
   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)
   SM: Keena Woods
   c. **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
   PI: Vicente Valero
   RN: Danielle Alanis

   **Second Line:**
   a. **2020-0685**: Randomized, Double-blind, Phase 3 Study of Tucatinib or Placebo in Combination with Ado-Trastuzumab Emtansine (T-DM1) for Subjects with Unresectable Locally Advanced or Metastatic HER2+ Breast Cancer HER2CLIMB-02)
   PI: Rashmi Murthy
   RN: Jennifer Childress
   SM: Keena Woods
   b. **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: Jennifer Childress

   **Third Line:**
   a. **2020-0685**: Randomized, Double-blind, Phase 3 Study of Tucatinib or Placebo in Combination with Ado-Trastuzumab Emtansine (T-DM1) for Subjects with Unresectable Locally Advanced or Metastatic HER2+ Breast Cancer HER2CLIMB-02)
   PI: Rashmi Murthy
   RN: Jennifer Childress
   SM: Keena Woods
b. 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  
c. 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: 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: Tarak Bhatt  
b. 2019-0668: A Phase I/II Dose-Escalation and Cohort-Expansion Study of Intravenous Zotatifin (eFT226) in Subjects with Selected Advanced Solid Tumor Malignancies  
PI: Funda Meric-Bernstam  
SM: Raquel Montelongo  
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: Ben Brugmann  
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) *ON HOLD*  
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) *ON HOLD*
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

\*h. **2020-0710**: A Phase 2 Study of VLS-101 in Patients with Solid Tumors
PI: Funda Meric-Bernstam
SM: Amanda Eckert

\*i. **2020-0489**: A Phase I, First-In-Human, Multicenter, Open-Label, Study of GQ1001, a HER2 Targeted Antibody-Drug Conjugate, Administered Intravenously in Adult Patients with HER2-Positive Advanced Solid Tumors
PI: Sarina Piha-Paul
SM: Ben Brugmann

\*j. **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

\*k. **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

\*l. **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

\*m. **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

Updated 05/28/2021
n. **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

o. **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 (1st Line)**
   PI: Senthil Damodaran
   RN: Danielle Alanis

2. **Metastatic HR Positive (>1st 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
   PI: Rachel Layman
   RN: Danielle Alanis
   d. **2019-0496**: A Multi-Center, Open-Label, Phase 1/1B 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
   SM: Gil Guerra

Updated 05/28/2021
IMMUNOTHERAPY

1. **Metastatic**
   a. 2017-0500: A Phase 1b Trial of M7824 and Eribulin in Patients with Metastatic Triple Negative Breast Cancer (TNBC)
      PI: Jennifer Litton
      RN: Jill Schwartz-Gomez

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
      SM: Angela Alexander

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

5. **ESR1 Mutations**

Updated 05/28/2021
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: Senthil Damodaran
   RN: Jill Schwartz-Gomez

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: Senthil Damodaran
   RN: Jill Schwartz-Gomez
   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: Naoto Ueno
   SM: Gil Guerra
   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: Danielle Kwiatkowski
   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
   SM: Angela Alexander
   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
   SM: Gil Guerra

Updated 05/28/2021
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: Senthil Damodaran
      RN: Jill Schwartz-Gomez

   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: Naoto Ueno
      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
      SM: Angela Alexander

   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. **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
      SM: Gil Guerra

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: Jennifer Childress
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: Jill Schwartz-Gomez

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
      SM: Angela Alexander
   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. 2018-0493: An Open-Label, Multicenter, Phase1b/2 Study of Rebastinib (DCC-2036) in Combination with Paclitaxel to Assess Safety, Tolerability and Pharmacokinetics in Patients with Advanced or Metastatic Solid Tumors
      PI: Naoto Ueno/Filip Janku
      RN: Angela Marx
   d. 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
      SM: Gil Guerra
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

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

Updated 05/28/2021