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 02/04/2021
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)
   RN: Jill Schwartz-Gomez
   
   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:**
   **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

   **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/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) *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) (*Phase1)
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. 2020-0480: 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

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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: Aaron Spike  

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  

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  

**HR POSITIVE BREAST CANCER TRIALS:**  

1. **Metastatic HR Positive (1st Line)**  
      PI: Senthil Damodaran  
      RN: Danielle Alanis  
   
   b. **2020-0786**: An Open-Label, Multicenter Study Evaluating the Safety of Lasofoxine in Combination with Abemaciclib for the Treatment of Pre- and Postmenopausal Women with Locally Advanced or Metastatic ER+/HER2- Breast Cancer with ESR1 Mutation (ELAINE II)  
      PI: Senthil Damodaran  
      SM: Danielle Kwiatkowski  

2. **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  

Updated 02/04/2021
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. **2018-0828**: 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: Jennifer Childress  

e. **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  

f. **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  

g. **2020-0786**: An Open-Label, Multicenter Study Evaluating the Safety of Lasofoxine in Combination with Abemaciclib for the Treatment of Pre- and Postmenopausal Women with Locally Advanced or Metastatic ER+/HER2- Breast Cancer with ESR1 Mutation (ELAINE II)  
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: Jill Schwartz-Gomez  

Updated 02/04/2021
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 Alfatatt

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**
   a. **2020-0786**: An Open-Label, Multicenter Study Evaluating the Safety of Lasofoxine in Combination with Abemaciclib for the Treatment of Pre- and Postmenopausal Women with Locally Advanced or Metastatic ER+/HER2- Breast Cancer with ESR1 Mutation (ELAINE II)
      PI: Senthil Damodaran
      SM: Danielle Kwiatkowski

**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: Jill Schwartz-Gomez

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b. 2019-1208: A Multicenter, Phase 2 Study of Tesetaxel Plus Three Different PD-(L)1 Inhibitors in Patients with Triple-Negative, Locally Advanced or Metastatic Breast Cancer and Tesetaxel Monotherapy in Elderly and Non-Elderly Adult Patients with HER2 Negative, Locally Advanced or Metastatic Breast Cancer
PI: Meghan Karuturi
RN: Jennifer Childress

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: 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
   RN: Anne Marie Norman
   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
   RN: Anne Marie Norman
   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. **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: Jennifer Childress  

h. **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

i. **2020-0017**: A Multicenter, Open-Label 1/2 Trial Evaluating the Safety, Tolerability, and Efficacy of MORAb-202, a Folate Receptor Alpha (FRα) – Targeting Antibody-drug Conjugate (ADC) in Participants with Selected Tumor Types  
   PI: Naoto Ueno  
   RN: Anne Marie Norman

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: 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  
      RN: Anne Marie Norman  
      SM: Gil Guera  
   c. **2016-0538**: Phase Ia 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

g. **2020-0017**: A Multicenter, Open-Label 1/2 Trial Evaluating the Safety, Tolerability, and Efficacy of MORAb-202, a Folate Receptor Alpha (FRα) – Targeting Antibody-drug Conjugate (ADC) in Participants with Selected Tumor Types  
   PI: Naoto Ueno  
   RN: Anne Marie Norman

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

Updated 02/04/2021
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 Cobimetinib 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 (DCC2036) 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
      RN: Anne Marie Norman
      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 02/04/2021