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

Updated 09/05/2018
HER2 POSITIVE BREAST CANCER TRIALS:

1. **Metastatic HER2 Positive**
   - **First Line:**
     a. **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: Pamela Nichols

     b. **2016-0537** A Phase1b Study of Neratinib, Pertuzumab and Trastuzumab with Taxol (3HT) in Primary Metastatic and Locally Advanced Breast Cancer, and Phase II Study of 3HT Followed by AC in HER2+ Primary IBC, and Neratinib with Taxol (NT) Followed by AC in HR+/HER- Primary IBC *(Note: Cohort 1 Phase 1b Any number of lines)*
        
        PI: Bora Lim
        RN: Angela Marx

   - **Third Line:**
     a. **2016-0054** (BMO)Phase II Randomized, Double-Blinded, Controlled Study of ONT-380 vs. Placebo in Combination with Capecitabine and Trastuzumab in Patients with Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma *(Note: prior Trastuzumab, Pertuzumab, TDM1; brain mets allowed; no prior Capecitabine; no prior lapatinib within 1 year)*
        
        PI: Rashmi Murthy *(Stacy Moulder)*
        SM: Samantha Zarda

   - **Any Line:**
     a. **2017-0820** A Phase 2, Multicenter, Open-Label Study of DS-8201a, an Anti-HER2 Antibody Drug Conjugate (ADC) for HER-Positive, Unresectable and/or Metastatic Breast Cancer Subjects Previously Treated with T-DM1
        
        PI: Rashmi Murthy/ *(Naoto Ueno)*
        SM: Samantha Zarda

     b. **2016-0537** A Phase1b Study of Neratinib, Pertuzumab and Trastuzumab with Taxol (3HT) in Primary Metastatic and Locally Advanced Breast Cancer, and Phase II Study of 3HT Followed by AC in HER2+ Primary IBC, and Neratinib with Taxol (NT) Followed by AC in HR+/HER- Primary IBC *(Note: Cohort 1 Phase 1b Any number of lines)*
        
        PI: Bora Lim
        RN: Angela Marx

     c. **2013-0114** Benefit of 2D-Strain Surveillance during Chemotherapy for Improving Cardiovascular Outcomes
        
        PI: Jose Banchs
        RN: Evguenia Gachimova
ICT (Any Line)
a. **2016-0532** Phase 1 Trial of ZW25 in Patients with Locally Advanced (Unresectable) and/or Metastatic HER2–Expressing Cancers (Note: Open Enrollment/Multiple Slots Available; Allows enrollment of HER2+ and HER2 low expression (IHC 2+; FISH negative will need biopsy to confirm)(*Phase 1)
   PI: Funda Meric-Bernstam
   RN: Kavitha Balaji

b. **2017-0994** A Phase 1/2, Open-label, Multicenter Study to Investigate the Safety, Pharmacokinetics, and Efficacy of TAS0728, An Oral Covalent Binding Inhibitor of HER2 in Subjects with Advanced Solid Tumors with HER2 or HER3 Abnormalities )(*Phase 1)
   PI: Sarina Piha-Paul
   SM: Qianqian Wang

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: Binoj Chandrasekharan; Rosa Mostorino

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
   SM: Michelle Bhatt

f. **2014-0119** Combination Treatment with Everolimus, Letrozole and Trastuzumab in Hormone Receptor and HER2/neu-positive Patients with Advanced Metastatic Breast Cancer and Other Solid Tumors: Evaluating Synergy and Overcoming Resistance (Note: for HR+/HER2+)(*Phase 1)
   PI: Filip Janku
   SM: Veronica Holley

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: Washout is 140 days from Trastuzumab; also enrolling HR+ and TNBC patients)(*Phase1)
   PI: Timothy Yap
   SM: Anjali Raina
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: Rachel Layman
   RN: Leah Murphy
   b. **2016-0419** Phase 1b Study to Assess the Safety, Tolerability, and Clinical Activity of Gedatolisib in Combination with Palbociclib and Either Letrozole or Fulvestrant in Women with Metastatic or Locally Advanced/Recurrent Breast Cancer (MBC)-B2151009
   PI: Rachel Layman
   SM: Gil Guerra
   c. **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
   d. **PA17-0217** POLARIS: Palbociclib in Hormone Receptor Positive Advanced Breast Cancer: A Prospective Multicenter Non-Interventional Study (NIS)
   PI: Meghan Karuturi
   SM: Danielle Kwiatkowski

2. **Metastatic Premenopausal HR Positive (1st Line)**
   a. **2016-0419** Phase 1b Study to Assess the Safety, Tolerability, and Clinical Activity of Gedatolisib in Combination with Palbociclib and Either Letrozole or Fulvestrant in Women with Metastatic or Locally Advanced/Recurrent Breast Cancer (MBC)-B2151009
   PI: Rachel Layman
   SM: Gil Guerra
   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
   c. **PA17-0217** POLARIS: Palbociclib in Hormone Receptor Positive Advanced Breast Cancer: A Prospective Multicenter Non-Interventional Study (NIS)
   PI: Meghan Karuturi
   SM: Danielle Kwiatkowski

Updated 09/05/2018
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. **2016-0419** Phase 1b Study to Assess the Safety, Tolerability, and Clinical Activity of Gedatolisib in Combination with Palbociclib and Either Letrozole or Fulvestrant in Women with Metastatic or Locally Advanced/Recurrent Breast Cancer (MBC)-B2151009
      PI: Rachel Layman
      SM: Gil Guerra
   c. **2016-0260** A Phase 1/1b, Open Label Study of LSZ102 Single Agent and LSZ102 in Combination with Either LEE011 (LSZ102 + BYL719) in Patients with Advanced or Metastatic ER+ Breast Cancer Who Have Progressed After Endocrine Therapy
      PI: Rachel Layman
      SM: Ketevan Gasitashvili
   d. **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
   e. **2016-0838** A Phase 3 Open-Label, Randomized, Multicenter Study of NKTR-102 versus Treatment of Physician’s Choice (TPC) in Patients with Metastatic Breast Cancer Who Have Stable Brain Metastases and Have Been Previously Treated with an Anthracycline, A Taxane, and Capecitabine *(Note: for HR+/HER2- and TNBC)(On Hold Pending Amendments)*
      PI: Nuhad Ibrahim
      SM: Ameena Manzoor
   f. **PA17-0217** POLARIS: Palbociclib in Hormone Receptor Positive Advanced Breast Cancer: A Prospective Multicenter Non-Interventional Study (NIS)
      PI: Meghan Karuturi
      SM: Danielle Kwiatkowski
   g. **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

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. **2016-0419** Phase 1b Study to Assess the Safety, Tolerability, and Clinical Activity of Gedatolisib in Combination with Palbociclib and Either Letrozole or Fulvestrant in Women with Metastatic or Locally Advanced/Recurrent Breast Cancer (MBC)-B2151009  
PI: Rachel Layman  
SM: Gil Guerra

c. **2016-0260** A Phase 1b, Open Label Study of LSZ102 Single Agent and LSZ102 in Combination with Either LEE011 (LSZ102 + BYL719) in Patients with Advanced or Metastatic ER+ Breast Cancer Who Have Progressed After Endocrine Therapy  
PI: Meghan Karuturi  
SM: Ketevan Gasitashvili

d. **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

e. **2016-0838** A Phase 3 Open-Label, Randomized, Multicenter Study of NKTR-102 versus Treatment of Physician’s Choice (TPC) in Patients with Metastatic Breast Cancer Who Have Stable Brain Metastases and Have Been Previously Treated with an Anthracycline, A Taxane, and Capecitabine (Note: for HR+/HER2- and TNBC)  
PI: Nuhad Ibrahim  
SM: Ameena Manzoor

f. **PA17-0217** POLARIS: Palbociclib in Hormone Receptor Positive Advanced Breast Cancer: A Prospective Multicenter Non-Interventional Study (NIS)  
PI: Meghan Karuturi  
SM: Robin Griner

**IMMUNOTHERAPY**

1. **Metastatic**
   
a. **2016-0386** Phase 1/2 Multicenter Trial of ICOS Agonist Monoclonal Antibody (mAb) JTX-2011 Alone or in Combination With Nivolumab in Adult Subjects with Advanced Refractory Solid Tumor Malignancies *(Note: Screening On Hold)*  
PI: Timothy Yap  
RN: Leah Murphy

b. **2016-0753** A Phase 1/2, Open-Label, multicenter, Dose Escalation and Dose Expansion Study of NKTR-214 and Nivolumab in Patients with Select Locally Advanced or Metastatic Solid Tumor Malignancies *(Note: Screening On Hold)*  
PI: Nuhad Ibrahim  
RN: Jill Schwartz-Gomez

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 09/05/2018*
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
   b. **2016-0683** Women’s Triple-Negative First-Line Study: A Phase II Trial of Mirvetuximab Soravtansine in Patients with Localized Triple-Negative Breast Cancer (TNBC) with Tumors Predicted Insensitive to Standard Neoadjuvant Chemotherapy (NACT), Including a Lead-in Cohort to Establish Activity in Patients with Metastatic TNBC
      PI: Stacy Moulder
      RN: Alyson Clayborn
   c. **2016-0753** A Phase 1/2, Open-Label, multicenter, Dose Escalation and Dose Expansion Study of NKTR-214 and Nivolumab in Patients with Select Locally Advanced or Metastatic Solid Tumor Malignancies (Note: Screening On Hold)
      PI: Nuhad Ibrahim
      RN: Jill Schwartz-Gomez
   d. **2017-0728**: A Multicenter Phase II Study of the Glutaminase Inhibitor CB-839 in Combination with Paclitaxel in Patients with Advanced Triple Negative Breast Cancer (TNBC) Including Patients of African Ancestry and Non-African Ancestry (Please consider as priority if patient is African-American)
      PI: Bora Lim
      RN: Charla Parker
      SM: Ameena Manzoor

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. **2016-0683** Women’s Triple-Negative First-Line Study: A Phase II Trial of Mirvetuximab Soravtansine in Patients with Localized Triple-Negative Breast Cancer (TNBC) with Tumors Predicted Insensitive to Standard Neoadjuvant Chemotherapy (NACT), Including a Lead-in Cohort to Establish Activity in Patients with Metastatic TNBC
      PI: Stacy Moulder
      RN: Alyson Clayborn
   c. **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: Ameena Manzoor

Updated 09/05/2018
d. **2016-0753** A Phase 1/2, Open-Label, multicenter, Dose Escalation and Dose Expansion Study of NKTR-214 and Nivolumab in Patients with Select Locally Advanced or Metastatic Solid Tumor Malignancies *(Note: Screening On Hold)*
   PI: Nuhad Ibrahim
   RN: Jill Schwartz-Gomez

e. **2016-0386** Phase 1/2 Multicenter Trial of ICOS Agonist Monoclonal Antibody (mAb) JTX-2011 Alone or in Combination With Nivolumab in Adult Subjects with Advanced Refractory Solid Tumor Malignancies *(Note: Screening On Hold)*
   PI: Timothy Yap
   RN: Leah Murphy

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: Ameena Manzoor
   c. **2016-0386** Phase 1/2 Multicenter Trial of ICOS Agonist Monoclonal Antibody (mAb) JTX-2011 Alone or in Combination With Nivolumab in Adult Subjects with Advanced Refractory Solid Tumor Malignancies *(Note: Screening On Hold)*
      PI: Timothy Yap
      RN: Leah Murphy
   d. **2017-0728**: A Multicenter Phase II Study of the Glutaminase Inhibitor CB-839 in Combination with Paclitaxel in Patients with Advanced Triple Negative Breast Cancer (TNBC) Including Patients of African Ancestry and Non-African Ancestry *(Please consider as priority if patient is African-American) (On Hold for Interim Analysis)*
      PI: Bora Lim
      RN: Christine Samuel

4. **Metastatic TNBC and Chest wall Metastasis**
   a. **2014-0034** Phase II using T-VEC as single agent for IBC or non-IBC with inoperable local recurrence *(Note: Screening On Hold)*
      PI: Naoto Ueno
      RN: Angela Marx

---

Updated 09/05/2018
BREAST CANCER WITH BRAIN METASTASIS

1. HER2+ (BMO)
   a. 2016-0054 (BMO) Phase II Randomized, Double-Blinded, Controlled Study of ONT-380 vs. Placebo in Combination with Capecitabine and Trastuzumab in Patients with Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma (Note: prior Trastuzumab, Pertuzumab, TDM1; brain mets allowed; no prior Capecitabine; no prior lapatinib within 1 year)
   PI: Rashmi Murthy (Stacy Moulder)
   SM: Samantha Zarda

2. HER2- (BMO)
   a. 2016-0838 A Phase 3 Open-Label, Randomized, Multicenter Study of NKTR-102 versus Treatment of Physician’s Choice (TPC) in Patients with Metastatic Breast Cancer Who Have Stable Brain Metastases and Have Been Previously Treated with an Anthracycline, A Taxane, and Capecitabine (Note: for HR+/HER2- and TNBC)
   PI: Nuhad Ibrahim
   SM: Ameena Manzoor

4. Active CNS Radiation Oncology Trials Enrolling Breast Patients
   http://inside.mdanderson.org/departments/cns-metastases-program/research.html
   PI: Jing Li
   RN: Mara Castaneda
   PI: Jing Li
   RN: Merin George

BRCA BREAST CANCER TRIALS

1. Metastatic

INFLAMMATORY BREAST CANCER

1. HER2-/ER+, HER2+/Any HR
   a. 2016-0537 A Phase1b Study of Neratinib, Pertuzumab and Trastuzumab with Taxol (3HT) in Primary Metastatic and Locally Advanced Breast Cancer, and Phase II Study of 3HT Followed by AC in HER2+ Primary IBC, and Neratinib with Taxol (NT) Followed by AC in HR+/HER- Primary IBC
   PI: Bora Lim
   RN: Angela Marx

Updated 09/05/2018
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. 2016-0890 A Phase II Study of Triple Combination of Atezolizumab + Cobimetinib + Eribulin (ACE) In Patients with Chemotherapy Resistant Metastatic Inflammatory Breast Cancer
      PI: Bora Lim
      SM: Angela Alexander
   c. 2014-0034 Phase II using T-VEC as single agent for IBC or non-IBC with inoperable local recurrence (On Screening Hold)
      PI: Naoto Ueno
      RN: Angela Marx
   d. 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