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: Keena Woods  
   b. [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 *ON HOLD*  
   PI: Vicente Valero  
   RN: Danielle Alanis

2. **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

3. **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 *ON HOLD*  
   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: Kathleen Kong

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. **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

d. **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

e. **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

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

g. **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
h. **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

i. **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

j. **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

k. **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

l. **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

m. **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
   b. **2020-1173**: EMBER: A Phase 1a/1b Study of LY3484356 Administered as Monotherapy and in Combination with Anticancer Therapies for Patients with ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers
      PI: Rachel Layman
      RN: Heather Alonzo
2. Metastatic HR Positive (>1st Line)
   a. **2017-0918**: Phase 1A 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-CS Alone and in Combination with Palbociclib in Subjects with ER+/HER2 Negative Advanced Breast Cancer
      PI: Rachel Layman
      RN: Danielle Alanis
   d. **2020-1173**: EMBER: A Phase 1a/1b Study of LY3484356 Administered as Monotherapy and in Combination with Anticancer Therapies for Patients with ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers
      PI: Rachel Layman
      RN: Heather Alonzo
   e. **2021-0033**: Evaluation of Talazoparib, a PARP Inhibitor, in Patients with Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial
      PI: Senthil Damodaran
      SM: Makeba Faniel
   f. **2020-0245**: REINA: A Phase I Study of Radiation Enhanced IL 12-Necrosis Attraction in Hormone Receptor Positive, HER2 Negative Metastatic Breast Cancer Patients
      PI: Meghan Karuturi
      RN: Jill Schwartz-Gomez

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
      RN: Vivian Chiv

Updated 09/28/2021
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**

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**

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
   b. [2020-1167](#): An Open-label Phase 1b Study of ORIC-101 in Combination with Anticancer Therapy in Patients with Advanced or Metastatic Solid Tumors-Part II
   PI: Naoto Ueno
   RN: Jennifer Childress
   c. [2020-0691](#): EPIK-B3: A Phase III, Multicenter, Randomized, Double-blind, Placebo Controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719), in Combination with Nab-paclitaxel in Patients with Advanced Triple Negative Breast Cancer with Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation
   PI: Debasish Tripathy
   RN: Jennifer Childress

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2. **Second Line Metastatic TNBC**

   a. **2020-0691**: EPIK-B3: A Phase III, Multicenter, Randomized, Double-blind, Placebo Controlled Study to Assess the Efficacy and Safety of Alpelisib (BYL719), in Combination with Nab-paclitaxel in Patients with Advanced Triple Negative Breast Cancer with Either Phosphoinositide-3-kinase Catalytic Subunit Alpha (PIK3CA) Mutation or Phosphatase and Tensin Homolog Protein (PTEN) Loss Without PIK3CA Mutation
   
   **PI:** Debasish Tripathy
   **RN:** Jennifer Childress

   b. **2021-0145**: An Open-Label, Phase 1b/2 Study to Evaluate the Safety and Efficacy of Fruquintinib in Combination with Tislelizumab in Patients with Advanced Triple Negative Breast Cancer
   
   **PI:** Haven Garber
   **RN:** Alyson Clayborn

   c. **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

   d. **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

   e. **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

   f. **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

   g. **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

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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

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)

Updated 09/28/2021
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  
   RN: Danielle Alanis

**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: Vivian Chiv  
   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. [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: Vivian Chiv  
   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

2. **ABC Registry**
   a. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center  
   PI: Abbey Kaler  
   SM: Makeba Faniel

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