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 01/24/2022
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
      PI: Vicente Valero
      RN: Danielle Alanis

Second Line:
   a. 2021-0327: A Phase 1, First in Human Study of Adenovirally Transduced Autologous Macrophages Engineered to Contain an Anti-HER2 Chimeric Antigen Receptor in Subjects with HER2 Overexpressing Solid Tumors
      PI: Naoto Ueno
      SM: Angela Alexander

Third Line:
   a. 2021-0327: A Phase 1, First in Human Study of Adenovirally Transduced Autologous Macrophages Engineered to Contain an Anti-HER2 Chimeric Antigen Receptor in Subjects with HER2 Overexpressing Solid Tumors
      PI: Naoto Ueno
      SM: Angela Alexander
   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. 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 (Note: Only HER2+/HR+ cohorts are currently open)
      PI: Rachel Layman
      RN: Heather Alonzo

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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: Chemo combos available with Capecitabine, Vinorelbine, and Tucatinib/Capecitabine; HER2 3+ or HER2 2+/FISH positive; must have received prior therapy with Trastuzumab, Pertuzumab, and T-DM1) (*Phase 1)*

   PI: Funda Meric-Bernstam
   SM: Kathleen Kong

b. **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

c. **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

d. **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

e. **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

f. **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

g. **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 *(Note: Allows HER2 2+ and 3+ FISH negative and gene amplification)*

   PI: Ecaterina Dumbrava
   SM: Amber Kennon

Updated 01/24/2022
h. **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

i. **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

j. **2021-0298**: A Phase 1b/2, 2-part Open-label Study to Assess the Safety and Antitumor Activity of Zanidatamab in Combination with ALX148 in Advanced HER2-expressing Cancer (*Phase1)
   PI: Funda Meric-Bernstam
   SM: Kathleen Kong

k. **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) (Note: Allows HER2 1+, 2+, 3+)
   PI: Ecaterina Dumbrava
   SM: Afzal Ahrorov

l. **2021-0455**: A Phase 1/1b Open-label, First-in-Human, Single Agent, Dose Escalation and Expansion Study for the Evaluation of Safety, Pharmacokinetics, Pharmacodynamics, and Anti-tumor Activity of SAR443216 in Participants with Relapsed/Refractory HER2 Expressing Solid Tumors (Note: Allows non-symptomatic untreated brain mets and selects for HER2 1+, 2+ 3+ or HER2 activating mutations)
   PI: Ecaterina Dumbrava
   SM: Amber Kennon

m. **2020-0764**: A Modular Phase I/IIa, Open-label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Efficacy of Ascending Doses of AZD5305 as Monotherapy and in Combination with Anti-cancer Agents in Patients with Advanced Solid Malignancies (PETRA)
   PI: Timothy Yap
   RN: Danielle Garcia
   SM: Akosua Badu-Nkansah

**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 *(Note: Only HER2+/HR+ cohorts are currently open)*  
PI: Rachel Layman  
RN: Heather Alonzo  

c. **2019-0999**: A Phase ½ 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 *ON HOLD*  
PI: Rachel Layman  
RN: Danielle Alanis  

d. **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  

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
IMMUNOTHERAPY

1. Metastatic
2. Metastatic – IBC/TNBC
   a. 2014-0533: A Phase 2 Study of Anti-PD1 (MK-3475) Therapy in Patients with Metastatic Inflammatory Breast Cancer (IBC) or Non-IBC Triple Negative Breast Cancer (TNBC) Who Have Received Clinical response or Stable Disease to Prior Chemotherapy
      PI: Naoto Ueno
      RN: Vivian Chiv

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. 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

Updated 01/24/2022
2b. **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

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. **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: Vivian Chiv
      SM: Gil Guerra
   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
      RN: Jennifer Childress
   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: Vivian Chiv
   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

Updated 01/24/2022
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
   RN: Alyson Clayborn

3. **≥3 Lines for mTNBC**
   a. **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: Vivian Chiv
   SM: Gil Guera
   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. **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: Vivian Chiv
   d. **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
   e. **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
   RN: Alyson Clayborn

4. **Metastatic TNBC and Chest wall Metastasis**

**BREAST CANCER WITH BRAIN METASTASIS**

1. **HER2+ (BMO)**
2. **HER2- (BMO)**
   a. **2021-0836**: A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC#820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases
   PI: Nuhad Ibrahim
   RN: Jennifer Childress

Updated 01/24/2022
3. **LMD HER2+(BMO)**
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: 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
   d. **2021-0077**: A Phase Ib/II Study of Grapiprant (IK-007) and Eribulin Combination Treatment for Metastatic Inflammatory Breast Cancer (mIBC)
   PI: Naoto Ueno
   RN: Angela Marx
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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PI – Primary Investigator
RN – Registered Nurse
SM – Study Manager
BMO – Breast Medical Oncology
LMD – Leptomeningeal Disease
CNS – Central Nervous System

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Updated 01/24/2022