Breast Cancer Research Program

Women's Cancer Developmental Therapeutics (WCDT) Program

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Contact WCDT Program Nurse Navigator for patient referral or to request additional information.

Visit our website to request more information or send us a referral:
http://tinyurl.com/WCDTProgram

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Metastatic Breast Cancer Clinical Trials

A. ER+ HER2-

a. Any Line

16-1001 A Phase 2 Trial of Fulvestrant (ER antagonist) plus Enzalutamide (AR Inhibitor) in ER+/HER2- Advanced Breast Cancer
(NCT02953860) PI Elias, Study Coordinator: Stephanie Armstead
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)

- Any number of prior lines of therapy, Measurable disease by RECIST
- Metastatic, candidate for fulvestrant, may have started fulvestrant within 3 months
- Postmenopausal or ovarian suppression
- Must have disease that can be biopsied, No history of seizures, treated brain mets allowed

b. First Line

16-0148 Phase 1B Study of Gedatolisib (PI3K/mTOR inhibitor) in Combination with Palbociclib (CDK4 & CDK6 inhibitor) and Either Letrozole (aromatase inhibitor) or Fulvestrant (ER antagonist) in Metastatic or Locally Advanced/Recurrent Breast Cancer
Pfizer (NCT02684032) PI: Kabos, Study Coordinator: Kyrie Dailey
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- Arm A first-line endocrine-based therapy only arm open
- Postmenopausal or Ovarian Suppression, ER+HER2-,
- measurable disease required
- No prior mTOR inhibitor or PI3K inhibitor, treated brain mets ok
- No more than 1 prior line of treatment for advanced metastatic disease

c. First or Second Line

17-2208 A Phase Ia/Ib, Multicenter, Open-Label, Dose Escalation, Dose Expansion Study of GDC-9545 (SERD) Alone or in Combination with Palbociclib (CDK4 & CDK6 inhibitor) and/or LHRH Agonist in Patients with Locally Advanced or Metastatic ER Positive Breast Cancer
(NCT03332797) PI: Kabos, Study Coordinator: Stephanie Armstead
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- Dose Expansion Cohorts A1 or A3 (post-menopausal) and Cohorts A2 and A4 (pre/peri-menopausal)
- Locally recurrent or metastatic breast cancer ER+HER2-
- Measurable or Evaluable Disease, treated brain mets are ok
- No more than 1 prior line of treatment for advanced or metastatic disease
- Metastatic recurrence on adjuvant endocrine therapy
- Advanced or metastatic ER+HER2- breast cancer that has recurred or progressed while being treated with adjuvant endocrine therapy for a duration of at least 24 months and/or endocrine therapy in the incurable, locally advanced, or metastatic setting and derived benefit from therapy (ie, tumor response or stable disease for at least 6 mos)

18-1404 Phase 1/2 Study of SAR439859 Single Agent and in Combination With Palbociclib in Postmenopausal Women With Estrogen Receptor Positive Advanced Breast Cancer
Sanofi TED14856 (NCT03284957) PI: Peter Kabos, Study Coordinator: Kari Corby

- Parts A & C closed
- Must be able to undergo biopsies
- ≤ 1 prior lines of chemotherapy in parts B & D
- Must have received 6 months of endocrine therapy in advanced setting
- ECOG 0-2
- Women only
- Postmenopausal
- Measurable disease by RECIST
- No prior CDK 4/6 inhibitor in part D

B. HER2+

a. Second or Third Line

18-0892 A randomized phase II study to evaluate efficacy of T-DM1 with or without Palbociclib in the treatment of patients with metastatic HER2 positive breast cancer
(NCT03530696) PI: Peter Kabos, Study Coordinator: Kyrie Dailey
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- Subjects should have received at least pertuzumab (neoadjuvant or metastatic setting)
- No prior treatment with CDK 4/6 inhibitors
- No prior treatment with T-DM1
- No more than 2 prior lines of therapy in the metastatic disease setting
- ECOG performance status 0-2
- CNS disease okay if clinically stable and completed radiotherapy, oral steroids for control are not allowed

C. TNBC

a. First or Second line

16-2105 SWOG S1416 Phase II Randomized, Placebo-Controlled Trial of Cisplatin (alkylating antineoplastic) with or Without ABT-888 (Veliparib—PARP Inhibitor) in Metastatic TNBC and/or BRCA-Mutation-Associated Breast Cancer
(NCT02595905) PI: Mayordomo, Study Coordinator: Stephanie Armstead
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Breast Cancer Research Team North (Medgyesy, Datko)
Breast Cancer Research Team South (Njiaju)

- TNBC or ER+HER2- with deleterious BRCA mutation
- 0-1 prior lines of therapy
- Measurable or non-measurable disease
- CNS mets permitted if patient meets additional criteria → Brain Mets Cohort
- No prior treatment with cisplatin or PARP inhibitors

b. Second or Third Line

18-2466 A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080/MK-7902) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors (LEAP-005)
Merck (NCT03797326) *PI: Bradley Corr, Study Coordinator: Sheri Neu*
Phase I Research Team/Clinic Anschutz (Diamond)

- Has histologically or cytologically-documented TNBC, advanced (metastatic and/or unresectable) solid tumor that is incurable and for which prior standard systemic therapy has failed

- Has Lactate Dehydrogenase (LDH) <2.0 x Upper Limit of Normal (ULN)
- Must have adequate tumor tissue be confirmed at central laboratory (archival or fresh tissue)
- Must have progressed on or since the last treatment
- Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 within 7 days of study treatment initiation
- Has received 1 or 2 prior lines of therapy
- Cannot have received prior therapy with lenvatinib, an anti-PD-1, anti-PD-L1, or anti PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g. cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], Tumor necrosis factor receptor superfamily, member 4 [OX 40], tumor necrosis factor receptor superfamily member 9

c. Any Line

17-1099 Phase 2 Randomized Study of ABT-888 (Veliparib) and Atezolizumab Alone or with Homologous DNA Repair (HDR) TNBC
(NCT02849496) PI: Afghahi, Study Coordinator: Gloria Crawford
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- BRCA 1/2 mutation present, Her2 negative
- No prior treatment with PARP inhibitors or anti-PD-1/anti-PD-L1 antibodies
- ECOG 0-2
- Measurable disease by RECIST
- Asymptomatic, treated brain mets allowed
- No limit on prior lines of therapy

D. Multiple Subtypes

17-0512 Phase 1 Trial of ZW25 (ECD4 and ECD2) in Patients with Locally Advanced (Unresectable) and/or Metastatic HER2+ Cancers
Zymeworks (NCT02892123) PI Mayordomo, Study Coordinator: Kyrie Dailey
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova

- Part 1: Any locally advanced (unresectable) and/or metastatic HER2-expressing (HER2 1+, 2+, or 3+ by IHC) cancer that has progressed after receipt of all therapies known to confer clinical benefit
    - HER2-overexpressing (3+ by IHC) or HER2 2+ and FISH positive breast cancer must have progressed after prior treatment with trastuzumab, pertuzumab, and T-DM1
    - HER2-overexpressing (3+ by IHC) or HER2 2+ and FISH positive gastric cancer must have progressed after prior treatment with trastuzumab
- Part 3: Locally advanced (unresectable) and/or metastatic cancer as follows:
    - HER2 IHC 1+ or IHC2+/FISH- breast cancer patients who have received at least 1 and no more than 3 prior systemic chemotherapy regimens
    - HER2 IHC 3+ or IHC 2+/FISH+ breast cancer patients who have received prior therapy with trastuzumab, pertuzumab, and T-DM1, at least 1 and no more than 3 prior systemic chemotherapy regimens

    - HER2 IHC 2+ or 3+ FISH+ or FISH- gastric/GEJ cancer patients who have received at least 1 and no more than 3 prior systemic chemotherapy regimens.
- Measurable disease by RECIST, treated brain mets allowed
- Willing to undergo fresh biopsy

15-0801 My Pathways: An Open-Label Phase IIA Study Evaluating Trastuzumab (HER2/neu inhibitor)/Pertuzumab (HER2 inhibitor), Erlotinib (EGFR/TK inhibitor), Vemurafenib (B-Raf inhibitor)/Cobimetinib (MEK inhibitor), Vismodegid (Hedgehog inhibitor), Alectinib (ALK inhibitor), and Atezolizumab (PD-L1 binder) in Patients who have Advanced Solid Tumors with Mutations or Gene Expression Abnormalities Predictive of Response to one of these Agents

Genetech (NCT02091141) PI: Lam, Study Coordinator: Tate Closson-Niese

Molecular Oncology Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)

- Arm with atezolizumab in patients with elevated tumor mutation burden (>10 mutations/Mb as determined by any CLIA validated assay) open
- Excludes active or untreated brain mets. Must be stable for 1 month
- Measurable disease
- ECOG 0-1
- No available therapies that will convey clinical benefit or no suitable treatment options per treating physician's judgement

15-1111 EAY131 Molecular Analysis for Therapy Choice. NCI-MATCH. (Targeted drugs for specific molecular aberrations)

(NCT02465060) PI Lieu, Study Coordinator: Lauren Draper

Molecular Oncology Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)

- At least one prior line and no other therapy prolonging survival
- Measurable disease, treated brain mets allowed
- Biopsy required and if mutation then assigned to arm
- Arms: EGFR mut, MET ex 14 sk, EGFR T790M, ALK transloc, ROS1 transloc, mTOR mut, TSC1/2 mut, GNAQ/GNA11, SMO/PTCH1, cKIT mut, NTRK fus. Please speak with coordinator for details on open arms.

18-2334 A Phase 2 study of AZD1775, a WEE1 inhibitor, in Treating Patients With Advanced Refractory Solid Tumors With CCNE1 Amplification

UM1 Study NCI Protocol #: 10136 (NCT03253679)

PI: Brandon Bernard, Study Coordinator: Courtney Newbold

Molecular Oncology Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)

- Patients must have one of the histologically advanced solid tumors harboring CCNE1 amplification
- Diseases are refractory to, or do not have, standard-of-care therapy; or they declined standard-of-care therapy
- Measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1
- Eastern Cooperative Oncology Group (ECOG) performance status score of 0-1
- No prior treatment with wee1 kinase inhibition

- No symptomatic and uncontrolled metastasis in the central nervous system or leptomeningeal or lymphangitic carcinomatosis

E. Subcutaneous Metastasis Amenable to Intratumor Injection

17-0074 A Phase 1 Open-Label, Multicenter, Dose Escalation Study of mRNA-2416, a Lipid Nanoparticle Encapsulated mRNA encoding Human OX40L, for Intratumoral Injection to Patients with Advanced Malignancies
Moderna (NCT03323398), PI Jimeno, Study Coordinator: Matt O'Hern
Phase I Research Team/Clinic Anschutz (Diamond)

- Tumor Types: All Comers with Subcutaneous or cutaneous mass for injection
- Check with coordinator for slots

F. Radiation Studies

15-0136 A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer
(NCT02364557) PI Rabinovitch, Study Coordinator: Chelsea Schaefer
Rad Onc Research Team Anschutz (Fisher, Rabinovitch)
Rad Onc Research Team North
Rad Onc Research Team South

- ≤ 4 metastases seen on standard imaging within 60 days prior to registration when all metastatic disease is located within the following sites: peripheral lung; osseous (bone); spine; central lung; abdominal-pelvic **OR**
- ≤ 2 metastases seen on standard imaging within 60 days prior to registration when any one metastasis is located in one of the following sites: liver; mediastinal/cervical lymph node; At least 1 pathologically confirmed visualized on CT or PET/CT.

Stage I-III Breast Cancer Clinical Trials

A. Multiple subtypes

a. Neoadjuvant

10-0374 Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis 2
I-SPY 2 (NCT01042379) PI: Elias, Study Coordinator: Gloria Crawford
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- All Comers
- Imaging and Molecular Analysis
- Any HER2, ER/PR status

- Stage II or III or T4, any N, M0 or Regional Stage IV
- ≥ 2.5 IBC
- Measurable disease by RECIST

b. Adjuvant

15-2078 Study Evaluating the Pregnancy Outcomes and Safety of Interrupting Endocrine Therapy for Young Women with Endocrine Responsive Breast Cancer who Desire Pregnancy
POSITIVE (NCT02308085) PI Borges, Study Coordinator: Heather Nelson
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova

- ER+ and/or PR+
- Stage I-III
- 18 – 42 years of age
- Must have received 18-30 months endocrine therapy and enrolled within 1 month of stopping
- Desire for pregnancy

16-1240 Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer
BWEL (NCT02750826) PI: Brown, Study Coordinator: Lisa Lopez
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)
Breast Cancer Research Team North (Medgyesy, Datko)

- HER2-, Any ER/PR, diagnosed in last 12 months
    - ER- and PR-: T2 or T3 N0, T0-3N1-3. Note: Patients with T1, N1mi disease are NOT eligible.
    - ER+ and/or PR+: T0-3N1-3 or T3N0. Note: Patients with T1-2, N1mi disease are NOT eligible
- No insulin dependent DM, IBS or other digestive problems that interfere with study diet, no health issues that preclude physical activity
- BMI ≥ 27

16-2437 (Co-Op): A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: THE ABC TRIAL
(NCT02927249) PI: Borges, Study Coordinator: Kari Corby
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)
Breast Cancer Research Team North (Medgyesy, Datko)
Breast Cancer Research Team South (Njiaju)

- Stage II or III, no recurrence, diagnosed within the last 12 months
- HER2-, any ER/PR status okay

- No history of GI bleed, stroke, ulcers, afib, MI, grade 4 HTN, or other cancer in last 5 years

17-1750 NRG BR005 Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery
(NCT03188393) PI: Ahrendt, Study Coordinator: Gloria Crawford

- T1-T3, stage II and IIIA invasive ductal carcinoma and who have completed 8 wks neoadjuvant chemotherapy with a clinical complete response (by clinical examination)
- Must have achieved a complete or near complete radiologic tumor response on breast imaging with mammogram, ultrasound, and MRI
- Patients must be undergoing breast conserving therapy

B. ER+ HER2-

a. Neoadjuvant

18-1211 Study of Pembrolizumab (MK-3475) Versus Placebo in Combination With Neoadjuvant Chemotherapy & Adjuvant Endocrine Therapy in the Treatment of Early-Stage Estrogen Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative (ER+/HER2-) Breast Cancer (MK-3475-756/KEYNOTE-756)
(NCT03725059) PI: Diamond, Study Coordinator: Stephanie Armstead
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- Has a localized invasive breast ductal adenocarcinoma, confirmed by the local pathologist, that includes either T1c-T2 (tumor size ≥2 cm), clinical node stage (cN)1-cN2, or T3-T4, cN0-cN2. Note: Inflammatory breast cancer is allowed.
- Centrally confirmed ER+/HER2-, grade 2 or 3 with Ki67 ≥30%
- Male or female
- N3 excluded

16-1657 ALTERNATE Approaches for Clinical Stage II or III Estrogen Receptor Positive Breast Cancer Neoadjuvant Treatment in Postmenopausal Women: A Phase III Study
(NCT01953588) PI: Borges, Study Coordinator: Heather Nelson
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)
Breast Cancer Research Team North (Medgyesy, Datko)
Breast Cancer Research Team South (Njiaju)

- Fulvestrant (ER antagonist) + anastrozole (aromatase inhibitor)
- HER2- / ER+ only
- Clinical T2 – T4c, any N, M0
- Post-menopausal
- High risk Ki67 greater than 10%

16-1042 Randomized Phase II Trial of Preoperative Fulvestrant (ER antagonist) with or without Enzalutamide (AR Inhibitor) in ER+/HER2- Breast Cancer
(NCT02955394) PI: Elias, Study Coordinator: Gloria Crawford

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)

- Stage at least T2 or greater, postmenopausal or ovarian suppression
- No history of seizures, no anti-coags
- Must undergo biopsies

C. TNBC

b. Adjuvant

16-2594 S1418 A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab, PD-1 inhibitor) for TNBC with ≥ 1cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy
(NCT02954874) PI: Elias, Study Coordinator: Stephanie Armstead
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)
Breast Cancer Research Team North (Medgyesy, Datko)
Breast Cancer Research Team South (Njiaju)

- TNBC s/p neoadjuvant chemo residual disease > 1 cm and/or node positive
- Addition of adjuvant chemo allowed
- No prior immunotherapy
- Residual disease
- Radiation allowed but randomization should occur before starting

D. Radiation

13-2454 A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chest Wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy
(NCT01872975) PI: Rabinovitch, Study Coordinator: Chelsea Schaefer
Rad Onc Research Team Anschutz (Fisher, Rabinovitch)
Rad Onc Research Team North
Rad Onc Research Team South

- Previous treatment with anthracycline or taxane regimen, 8 weeks minimum
- HER2+ must have received neoadjuvant anti-HER2 therapy
- Lumpectomy or mastectomy with negative axillary nodes at that time

18-0627 Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation With Breast Reconstruction
(NCT03414970) PI: Rabinovitch, Study Coordinator: Chelsea Schaefer, Tess Santangelo
Rad Onc Research Team Anschutz (Fisher, Rabinovitch)

- Mastectomy and have involved lymph nodes per pathology
- Histologically confirmed invasive carcinoma of the breast - ductal, lobular, mammary, medullary or tubular allowed

- Eligible women include Final AJCC Stage IIa-IIIa (pathologic stage T0N1a-2a, T1N1a-2a, T2N1a-2a, T3N0-2a, all M0 status) Pathological stage for all patients not receiving neoadjuvant chemotherapy. Higher of the clinical or pathological T and N stage, if receiving neoadjuvant chemotherapy. Patients with pathological N0 at the time of mastectomy are only eligible if biopsy-proven clinically N1 or N2 disease is documented prior to induction chemotherapy.
- No significant post mastectomy complications requiring unplanned re-operation or admission for IV antibiotics

There are additional Phase I all comer trials available, please contact the Nurse Navigator for assistance.

Breast Providers	Location	Contact WCDT Navigator	Email
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