Breast Cancer Research Program
Women’s Cancer Developmental Therapeutics (WCDT) Program

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Visit our website to request more information or send us a referral:
http://www.ucdenver.edu/academics/colleges/medicalschoolcenters/cancercenter/CancerCare/WCDT/Pages/Women%E2%80%99s%20Cancer%20Developmental%20Therapeutics%20Program.aspx

Updated: March 1, 2018

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. Second Line

   16-0148 Phase 1B Study to Assess the Safety, Tolerability, and Clinical Activity of Gedatolisib (PI3K/mTOR inhibitor) in Combination with Palbociclib (CDK4 & CDK6 inhibitor) and Either Letrozole (aromatase inhibitor) or Fulvestrant (ER antagonist) in Women with Metastatic or Locally Advanced/Recurrent Breast Cancer
   Pfizer (NCT02684032) PI: Kabos, Study Coordinator: Emily Berens
   Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
   • Arm A first-line endocrine-based therapy
• Arm B second line, no prior CDKi
• Arm C second or third-line endocrine-based therapy with prior CDKi
• Postmenopausal or Ovarian Suppression, ER+HER2-, ≤ 1 prior lines of chemotherapy, prior CDK4/6 ok (Arm C), measureable disease required,
• No prior mTOR inhibitor or PI3K inhibitor, treated brain mets ok
• Check with coordinator for slots

16-1288 An Open-Label Phase II Study of MLN0128 (Torc1/2 inhib) in Combination with Fulvestrant (ER antagonist) in Women with ER+HER2 – Advanced or Metastatic Breast Cancer That Has Progressed During or After Aromatase Inhibitor Therapy
Millennium C31006 (NCT02756364) PI: Diamond, Study Coordinator: Adriana Brunet
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
• Prior treatment with 1-2 prior lines of endocrine therapy required
• ≤ 1 prior line of chemotherapy, postmenopausal, treated brain mets ok, measureable disease or sclerotic/osteoblastic bone only
• Expected to close to accrual 3/18

c. Third line and beyond

15-0356 RAD1901 (SERD) in Postmenopausal Women with Advanced ER Positive and HER-2 Negative Breast Cancer
Radius (NCT02338349) PI: Kabos, Study Coordinator: Emily Berens
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
• Part D open
• 2 or more lines of endocrine therapy required, 1 prior line of chemo allowed, measurable disease required
• Check with coordinator for slots

14-0583 A Phase I, Open-Label Study to Assess Ascending Doses of AZD5363 (Inhibitor of AKT 1, 2 and 3 AKT/PKB)
(NCT01226316) PI: Kabos, Study Coordinator: Brad McKay
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
• Arm F Open, Must be ER+ with mutation in PTEN
• Refractory to all standard previous treatments, at least one prior line of therapy
• Measurable disease by RECIST, Disease that could be biopsied post treatment initiation
• No prior PI3K or MTOR inhibitor, No diabetes (even if managed), treated brain mets allowed

B. HER2+

a. Second line

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
**T3 Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)**

- Excludes active or untreated brain mets. Must be stable for 1 month
- Measurable or evaluable disease
- ECOG 0-2
- HER2 overexpression, amplification, or HER2 activating mutation
- Check with coordinator for slots

**b. Third Line and beyond**

**16-1661 Phase Ib/II Open-Label Single Arm Study to Evaluate Safety and Efficacy of Tucatinib in Combination with Palbociclib (CDK4 & CDK6 inhibitor) and Letrozole (aromatase inhibitor) in Subjects with Hormone Receptor Positive and HER2-Positive Metastatic Breast Cancer**

Tucatinib (NCT03054363) PI Shagisultanova, Study Coordinator: Emily Berens

*Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)*

- Post-menopausal or ovarian suppression, ER+HER2+
- At least two approved HER2-targeted agents (trastuzumab, pertuzumab, or TDM-1) in the course of their disease with at least 1 line of prior HER2-targeted therapy in the metastatic setting, (see protocol for exceptions)
- Up to 2 lines of prior endocrine therapy in the metastatic setting are allowed. Prior adjuvant and/or neoadjuvant endocrine regimens are allowed and not counted towards this limit
- Measureable or Evaluable Disease

**15-1856 Phase 2 Randomized, Double-Blinded, ONT-380 (HER2 selective inhibitor) vs. Placebo in Combination with Capecitabine (PO antimetabolite antineoplastic) and Trastuzumab (HER2/neu inhibitor) in Patients with Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma (HER2CLIMB)**

ONT-206 (NCT02614794) PI Borges, Study Coordinator: Jonathan Scheiner

*Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)*

*Lone Tree Research Team (Brown)*

- Prior treatment with a taxane, trastuzumab, pertuzumab, and T-DM1
- No treatment with lapatinib within 12 months
- No prior treatment with neratinib, afatinib, or other investigational HER2/EGRF TKI
- Measurable or non-measurable disease
- Treated brain mets allowed

**c. Late line**

**17-0512 Phase 1 Trial of ZW25 (ECD4 and ECD2) in Patients with Locally Advanced (Unresectable) and/or Metastatic HER2+ Cancers – Part 2 – Cohort 2**

Zymeworks NCT02892123 PI Mayordomo, Study Coordinator: Adriana Brunet

*Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)*

- Part 2 must have HER2+ breast cancer
- Locally advanced (unresectable) and/or metastatic cancer that has progressed after receipt of all therapies known to confer benefit, Measurable disease by RECIST, treated brain mets allowed
- Willing to undergo fresh biopsy

**16-1665 Roche FAP – RO6874281 (IV – IL-2v targeting FAP) as single agent (Part A) or in Combination with Trastuzumab (HER2/neu inhibitor) or Cetuximab (EGFR Inhibitor) (Part B)**
(NCT02627274), PI Jimeno, Study Coordinator: Matt Lee
*Phase I Research Team/Clinic Anschutz (Diamond)*
- Her2-positive Breast / H&N
- Anti-HER2 targeted therapy as most recent line of treatment
- Check with coordinator for slots

### C. TNBC

#### a. First line

**16-1003 A Randomized, Double-Blind, Phase III Study of Pembrolizumab (MK-3475, PD-1 inhibitor) plus Chemo vs Placebo plus Chemo for Previously Untreated Locally Recurrent Inoperable or Metastatic TNBC**
*Keynote-355 (NCT03036488) PI: Diamond, Study Coordinator: Jonathan Scheiner
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)*
- 0 prior lines of therapy metastatic disease
- ≥ 6 months elapsed from curative treatment to metastatic recurrence
- Must have been treated with (neo)adjuvant anthracycline unless contraindicated
- Measurable disease by RECIST
- Treated brain mets allowed, requires central confirmation TNBC

#### b. 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: Emily Berens
*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

**16-2524 GO30103: A Phase 1a/1b Open-Label, Dose-Escalation study of the Safety and Pharmacokinetics of MTIG7192A (TIGIT binder) as a Single Agent and in Combination with Atezolizumab (PD-L1 binder) in Patients with Locally Advance or Metastatic Tumors**
*Genetech (NCT02794571) PI Kessler, Study Coordinator: Oliva Pearson
T3 Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)*
- Mandatory biopsy must test positive for PD-L1 and/or TIGIT
• Measurable disease required
• Only 1 prior line of therapy allowed

c. Second line and beyond

13-2176 A Multi-Center, Dose Finding, Open Label, Phase 1 Study of RX-5902 (P-p68 inhibitor) in Subjects with Advanced or Metastatic Solid Tumors
Rexahn (NCT02003092) PI Diamond, Study Coordinator: Adriana Brunet
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
  • No clinical evidence of brain metastasis
  • Refractory, Intolerant or ineligible to receive approved standard therapies
  • ECOG performance score ≤ 1
  • No uncontrolled diabetes
  • Measurable or evaluable disease
  • No documentation of Hep B, C, and HIV

16-2504 A Multicenter, Open-Label, Phase 2 Study of Imprime PGG (immunotherapy) and Pembrolizumab (PD-1 inhibitor) in subjects with Advanced Melanoma Failing Front-line Treatment with Checkpoint Inhibitors or TNBC Failing Front-Line Chemotherapy for Metastatic Disease
Biothera (NCT02981303) PI Borges, Study Coordinator: Adriana Brunet
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
  • At least 1 prior line of therapy
  • Prescreening req’d and must have IgG anti-β-glucan antibody (ABA) of ≥ 20 mcg/mL
  • Measurable disease, CNS mets allowed if treated and stable
  • No prior treatment with any anti-PD-1, anti-PD-L1, anti-CTLA-4, or anti-PD-L2 agents
  • PAMP

17-1501 An International, Multi-Center, Open-Label, Randomized, Phase III Trial of Sacituzumab Govitecan (Trop2 ADC) versus Treatment of Physicians Choice in Patients with Metastatic Triple-Negative Breast Cancer Who Received at Least Two Prior Treatments
IMMU-132 (NCT02574455) PI Diamond, Study Coordinator: Jonathan Scheiner
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
  • At least 2 prior lines of therapy (no max limit, adj counts for some)
  • Measurable disease, treated CNS mets allowed
  • Eligible for one of the chemotherapy options listed as TPC (Eribulin, capecitabine, gemcitabine, or vinorelbine)
  • Need to have been treated with a taxane in any setting
  • No Presence of bulky disease (defined as any single mass > 7 cm in its greatest dimension).

17-0339 BMS CA2099GW Phase 1/2 Study to Evaluate the Safety and Preliminary Efficacy of Nivolumab (PD-1 inhibitor) Combined with Daratumumab (IgG1) in Participants with Advanced or Metastatic Solid Tumors
(NCT03098550), PI Leong, Study Coordinator: Sarah Rippke
Phase I Research Team/Clinic Anschutz (Diamond)
- Tumor Types: TNBC, NSCLC, Panc
- 1-4 prior chemos
- 11 TNBC slots available 2/22/18; Check with coordinator for slots

D. Multiple Subtypes

15-1726 Phase 1 / 2 Open-Label Study of Seviteronel (ARi) in Patients with Advanced TNBC
Innocrin (NCT02580448) PI Elias, Study Coordinator: Jonathan Scheiner
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
- Male breast cancer ER+ or TNBC
- Any number of prior lines of therapy
- If ER+/HER2+, then at least one prior endocrine
- Measurable disease

15-1111 EAY131 Molecular Analysis for Therapy Choice. NCI-MATCH. (Targeted drugs for specific molecular aberrations)
(NCT02465060) PI Lieu, Study Coordinator: Lauren Draper
T3 Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)
- At least one prior line and no other therapy prolonging survival
- Measureable disease, treated brain mets allowed
- Biopsy required and if mutation then assigned to arm
- Arms: EGFR mut, MET amp, MET ex 14 sk, EGFR T790M, ALK transloc, ROS1 transloc, mTOR mut, TSC1/2 mut, GNAQ/GNA11, SMO/PTCH1, cKIT mut, CCNDI/2/3 amp, CDK4/6 AMP, Rb+; NTRK fus. Please speak with coordinator for details on open arms.

16-1089 An Open-Label Study of Rovalpituzumab Tesirine (targets DLL3) in Subjects with Delta-Like Protein 3-Expressing Advanced Solid Tumors
Stemcentrx (NCT02709889) PI Lewis, Study Coordinator: Olivia Pearson
T3 Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)
- DLL-3 expression positive prescreening (archival tissue sample accepted, low percentage of breast cancers are DLL3+)
- Measureable disease, relapsed refractory
- Check with coordinator for slots

16-2407 Phase 1, Open-Label Study of DCC-3014 to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Patients with Advanced Malignancies (i.v. CSFR-1 inhibitor to revert macrophage suppression) (Deciphera)
(NCT03069649) PI Leong, Study Coordinator: Lauren Draper
T3 Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)
- No limit on prior therapies
- Prefers patients with bone metastases and/or effusions
- Check with coordinator for slots

17-0948 A Phase 1 Trial of MK-7684 (TIGIT binder) as Monotherapy and in Combination with Pembrolizumab (PD-1 inhibitor) in Subjects with Advanced Solid Tumors
Merck TIGIT MK7684 (NCT02964013), PI Jimeno, Study Coordinator: Amanda Kupniewski
Phase I Research Team/Clinic Anschutz (Diamond)
- Locally advanced and unresectable or metastatic
- Any receptor status, including TNBC
- Must have received standard of care therapy, ≤ 3 lines
- No prior PD1/PD-L1 therapy
- Measurable disease
- Stable brain mets allowed
- 39 breast slots as of 2/22/18

**16-0277 A Phase I Open-Label, Non-Randomized, Dose-Escalating Safety, Tolerability, and Pharmacokinetic Study of TAS-119 (aurora A kinase inhibitor) in Combination with Paclitaxel (taxane chemotherapy) in Patients with Advanced Solid Tumors**
(NCT02134067), PI Diamond, Study Coordinator: Matt Lee
*Phase I Research Team/Clinic Anschutz (Diamond)*
- Expansion cohort in metastatic breast cancer refractory to prior taxane (progression on taxane)
- Up to 5 prior lines of chemo in metastatic setting
- Treated brain mets ok

**17-1909 A Study to Investigate the Bioequivalence or Relative Bioavailability of Three New Idasanutlin (MDM2 antagonist) Tablet Variants Following Oral Administration in Participants with Solid Tumors**
(NCT03362723), PI Villalobos, Study Coordinator: Nichole Adler
*Phase I Research Team/Clinic Anschutz (Diamond)*
- Tumor types: all comers
- QTcF greater than 440 excluded, plts must be 150

**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: Anne Martin
*Phase I Research Team/Clinic Anschutz (Diamond)*
- Tumor Types: All Comers with Subcutaneous or cutaneous mass for injection
- Check with coordinator for slots

**17-1452 A Phase I, open label, multicenter study of the safety and efficacy of MIW815 (STING) (ADU-S100) Administered by Intratumoral Injection to Patients with Advanced/Metastatic Solid Tumors or Lymphomas**
(Adura (NCT02675439), PI Messersmith, Study Coordinator: Tara Wells
*Phase I Research Team/Clinic Anschutz (Diamond)*
- Tumor Types: all comers with cutaneous or sub-cutaneous lesions
- Measureable disease and two biopsy accessible lesions (L1 1-10cm)
- One amenable to intratumoral injection
- Check with coordinator for slots

**F. Radiation Studies**

**15-0136 A Phase IIIR/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, Becky Kissane
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.

14-1261 A Phase 1 Study of Stereotactic Body Radiotherapy (SBRT) for the Treatment of Multiple Metastases
(NCT02206334) PI Rabinovitch, Study Coordinator: Chelsea Schaefer, Becky Kissane
Rad Onc Research Team Anschutz (Fisher, Rabinovitch)
• Metastatic breast cancer (MBC). The sites of allowed metastases are: peripheral lung, central lung, mediastinal/cervical lymph node, liver, spinal/paraspinal, osseous, and abdominal-pelvic
• The patient must meet ONE of the three following criteria:
  ▪ 3-4 radiographically distinct metastases of any distribution in the allowed anatomical sites OR
  ▪ 2 radiographically distinct metastases that must be anatomically close (i.e., with less than or equal to 5cm of normal tissue between them) OR
  ▪ 3 or 4 distinct metastases, 2 or 3 to be treated with SBRT and the other (s) having been surgically removed
• Metastatic location closed to accrual: Mediastinal/Cervical Lymph Node
• Metastatic locations open to accrual: Liver
• Metastatic locations conditionally open: Lung – peripheral; Osseous (Bone); Spinal/Paraspinal; Abdominal/Pelvic; Lung – Central
• The Dose Limiting Toxicity questions have been answered for Peripheral Lung, Spinal/Paraspinal, Osseous (Bone), Abdominal/Pelvic and Central Lung metastases and patients with ONLY those metastatic sites are no longer required for this trial. However, eligible patients who have Peripheral Lung, Spinal/Paraspinal, Osseous (bone), Abdominal/Pelvic, and/or Central Lung Metastasis AND the metastatic site currently open to accrual (Liver) can be enrolled.
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

**13-1617 INFORM: Randomized Phase II Trial of Neoadjuvant Cisplatin (alkylating antineoplastic) vs. Doxorubicin (anthracycline)/Cyclophosphamide (alkylating antineoplastic) in Women with Newly Diagnosed Breast Cancer and Germline BRCA Mutations**
(NCT01670500) PI: Borges, Study Coordinator: Jonathan Scheiner
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
- Deleterious BRCA mutation only, HER2 negative, any ER/PR
- Clinical T1 > 1 cm, T2 or T3, NO-3, M0
- Must undergo biopsy

b. Adjuvant

**14-1534 NRG B55 A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib (PARP inhibitor) Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy**
(NCT02032823) PI: Borges, Study Coordinator: Jonathan Scheiner
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
- BRCA mutation
- If surgery first and adjuvant chemo: TNBC node positive OR T2+ node negative, ER/PR+ HER2 – 4+ pathologically confirmed lymph nodes
- If neoadjuvant chemo: TNBC no pCR, ER/PR+HER2- non pCR AND CPS&EG score > 3
- No prior PARPi exposure

**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: Emily Berens
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: 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)
- 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

B. ER+ HER2-
a. Neoadjuvant

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: Emily Berens
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

b. Adjuvant

13-1448 S1207 Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the use of Adjuvant Endocrine Therapy +/- One Year of Everolimus (mTOR inhibitor) in Patients with High-Risk Hormone Receptor+ HER2- Breast Cancer
(NCT01674140) PI: Elias, Study Coordinator: Emily Berens
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)
• HER2- and ER/PR +
• Must have received and completed neoadjuvant or adjuvant chemotherapy
• Must be high risk as defined by: 4+ nodes, 1+ positive nodes after neoadjuvant chemo, 1-3+ nodes and oncotype > 25, mammoprint high, or high grade, node negative with T2+ and oncotype > 25 or high mammoprint.

C. TNBC

a. Neoadjuvant

16-2630 Phase III, Randomized, Double-blind Study to Evaluate Pembrolizumab (PD-1 inhibitor) plus Chemotherapy vs. Placebo plus Chemotherapy as Neoadjuvant Therapy and Pembrolizumab (PD-1 inhibitor) vs. Placebo as Adjuvant Therapy for Triple Negative Breast Cancer
(NCT03036488) PI: Diamond, Study Coordinator: Jonathan Scheiner
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)
Lone Tree Research Team (Brown)
• Centrally confirmed TNBC
• Locally advanced: T1cN1-2, T2-T4a-dN0-2

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: Emily Berens, 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, Becky Kissane
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

15-1329 Phase II Hypofractionated, Comprehensive Radiation Therapy for Node-Positive Breast Cancer
(NCT02700386) PI Fisher, Study Coordinator: Chelsea Schaefer, Tess Santangelo
Rad Onc Research Team Anschutz (Fisher, Rabinovitch)
• Have had either mastectomy or lumpectomy and have involved lymph nodes per pathology
• Eligible women include AJCC 7th ed. Stage cN0 or cN1 subsequently staged after surgery as Stage pIB (N1mic), pIIA, pIIB, pIIIa, pIIIb, or N3a (10 or more axillary nodes) only.
  • Note that women less than 50 years of age, women who received chemotherapy, patients staged as pN0 (i+ or mol+), and large-breasted women are eligible for enrollment.
• 180 days maximum between last surgery or last dose of adjuvant chemo and randomization

There are additional Phase I all comers trials available, please contact the Nurse Navigator for assistance.
<table>
<thead>
<tr>
<th>Breast CRCs</th>
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