

Breast Cancer Research Program

Women's Cancer Developmental Therapeutics (WCDT) Program

WCDT Program Nurse Navigator	Brandi Welker	720-848-9302	brandi.welker@uchealth.org
Breast Cancer Research Team Operational Manager	Melanie Schwartz	720-848-0653	Melanie.f.Schwartz@cuanschutz.edu
Molecular Oncology Therapeutics (formerly T3) Team Manager	Paula Fisk	720-848-0676	Paula.Fisk@ucdenver.edu
Phase I Research Team New Patient Intake Coordinator	Amanda Siedem	720-848-0052	Amanda.Siedem@ucdenver.edu
Radiation Oncology Research Team Project Manager	Robyn Swing	720-848-0607	robyn.swing@ucdenver.edu

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:

<https://medschool.cuanschutz.edu/colorado-cancer-center/clinical-trials/women's-cancer-developmental-therapeutic-program>

Updated: February 26, 2020

Metastatic Breast Cancer Clinical Trials

A. ER+ HER2-

b. 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

c. Second or Third Line

19-0327 Elacestrant Monotherapy vs. Standard of Care for the Treatment of Patients With ER+/HER2- Advanced Breast Cancer Following CDK4/6 Inhibitor Therapy: A Phase 3 Randomized, Open-label, Active-controlled, Multicenter Trial Radius (NCT03778931) PI: Kabos, Study Coordinator: Leah Adams

- Locally recurrent or metastatic breast cancer ER+HER2-
- Must be appropriate candidates for endocrine monotherapy
- Measurable disease, or nonmeasurable (evaluable) bone-only disease
- Must have received one and no more than two lines of endocrine therapy for advanced/metastatic breast cancer
- Must have received treatment with CDK4/6 inhibitor in combination with either fulvestrant or an aromatase inhibitor
- May have received no more than one line of chemotherapy in the advanced/metastatic setting
- Must have ctDNA ESR1-mut or ESR1-WT status as determined by central testing before randomization

18-2654 A Phase 1 Dose Escalation and Expansion Study of AZD9833 Alone or in Combination with Palbociclib in Women with ER Positive, HER2 Negative Advanced Breast Cancer

(NCT03616587) PI: Kabos, Study Coordinator: Kyrie Lopez

- No more than 2 lines of prior chemotherapy
- Prior CDK 4/6 permitted
- ECOG 0-1
- Must be able to undergo baseline and on-study biopsies
- Measurable disease by RECIST
- Can be pre or post-menopausal
- Recurrence or progression on at least one line of prior endocrine therapies (no limit to lines of endocrine therapy)
- There is no limit on the number of lines of prior endocrine therapies
- Limited slots in certain cohorts, please contact study coordinator for slot

d. Later Lines

19-0326 Phase 3 Study of Sacituzumab Govitecan vs Physician's Choice in Subjects With Hormonal Receptor-Positive Human Epidermal Growth Factor Receptor 2 Negative Metastatic Breast Cancer Who Have Failed at Least 2 Prior Chemotherapy Regimens (NCT03901339)

PI: Diamond Study Coordinator: Melissa Belford

- Refractory to or relapsed after at least 2 lines but no more than 4 systemic chemotherapy regimens for MBC. Recurrence within 12 months in adjuvant setting counts as 1 line of therapy in metastatic setting.
- Must have received a taxane in any setting, 1 hormonal therapy, and a CDK 4/6 inhibitor in the metastatic setting
- Measurable disease required
- Stable brain mets allowed
- No prior treatment with Topoisomerase I inhibitors as free form or other formulations

B. HER2+

a. First Line

19-1152 (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 (NCT03199885) PI: Elias, Study Coordinator: Kyrie Lopez

- De novo metastatic disease or recurrent disease with at least 6 months from completion of neoadjuvant/adjuvant HER2 targeted therapy
- Measurable disease required
- Central HER2 testing required
- CNS disease allowed
- No prior CDK4/6 inhibitor with endocrine therapy for metastatic disease

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 Lopez

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

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: Heather Nelson

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
- Limited slots available, contact study coordinator for slot confirmation

C. TNBC

b. Second or Third Line

18-1933 A Phase II, Open Label, Randomised, Multi-centre Study to Assess the Safety and Efficacy of Agents Targeting DNA Damage Repair in Combination With Olaparib Versus Olaparib Monotherapy in the Treatment of Metastatic Triple Negative Breast Cancer Patients Stratified by Alterations in Homologous Recombinant Repair (HRR)-Related Genes (Including BRCA1/2) (VIOLETTE)

(NCT03330847) PI: Afghahi, Study Coordinator: Heather Nelson

- Histologically or cytologically confirmed TNBC at initial diagnosis with evidence of metastatic disease and HER2 negative as per ASCO-CAP HER2 guideline recommendations 2013.
- Patients must have received at least 1 and no more than 2 prior lines of treatment for metastatic disease with an anthracycline (eg, doxorubicin, epirubicin) and/or a taxane (eg, paclitaxel, docetaxel) unless contraindicated, in either the neo-adjuvant, adjuvant or metastatic setting
- Confirmed presence of qualifying HRR mutation or absence of any HRR mutation in tumor tissue by the Lynparza HRR assay
- ECOG 0-1
- Measurable disease
- CNS mets permitted if stable
- No prior treatment with PARP inhibitors

c. Second, Third or Fourth Line

19-0207 An Open-Label, Multicenter, Phase 1b/2 Study of Rebastinib (DCC-2036) in Combination with Paclitaxel to Assess Safety, Tolerability, and Pharmacokinetics in Patients with Advanced or Metastatic Solid Tumors

Deciphera (NCT03601897) PI: Jennifer Diamond, Study Coordinator: Kari Corby
Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Part 2, Cohort 1: Triple-Negative Breast Cancer

- Histologically confirmed metastatic triple-negative breast cancer
- Received at least one prior line but no more than three prior lines of systemic chemotherapy in the metastatic setting
- Has not received taxane-containing regimens within 6 months prior to the first dose of study drug
- ECOG PS of ≤ 2
- Able to provide an archival tumor tissue sample

Part 2, Cohort 2: Inflammatory Breast Cancer (IBC)

- Histologically or cytologically confirmed stage IV breast

- carcinoma with a previous clinical diagnosis of IBC based on the presence of inflammatory changes in the involved breast, such as diffuse erythema and/or edema (peau d'orange), with or without an underlying palpable mass, and involving the majority of the skin of the breast; pathological evidence of dermal lymphatic invasion should be noted but is not required for diagnosis.
- Received at least one prior line of systemic chemotherapy in the metastatic setting.
 - Has not received taxane-containing regimens within 6 months prior to the first dose of study drug
 - ECOG PS of ≤ 2
 - Able to provide an archival tumor tissue sample

d. 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: Kari Corby

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

16-1333 A Phase I/IIa Trial With BMS-986158, a Small Molecule Inhibitor of the Bromodomain and Extra-Terminal (BET) Proteins, as Monotherapy or in Combination With Nivolumab in Subjects With Selected Advanced Solid Tumors or Hematologic Malignancies

(NCT02419417) PI: Jennifer Diamond, Study Coordinator: Amanda Kupniewski

Part 2: Triple Negative Breast Cancer (TNBC)

- Males and females with histologically or cytologically confirmed triple negative breast carcinoma as defined by ASCO/CAP guidelines
- Had progression or refractory disease during or after at least 1 chemotherapy regimen for the treatment of metastatic or locally advanced disease
- All subjects with **TNBC must have BRD amplification** in tumor cells
- Must be able to undergo biopsies
- ECOG 0-1

D. Multiple Subtypes

19-1118 A Phase 1, Open Label, Dose-Escalation and Expansion Study of Oral ORIN1001 With and Without Chemotherapy in the Treatment of Subjects With Solid Tumors (NCT03950570)

PI: Anthony Elias, Study Coordinator: Kyrie Lopez

- Males or females with relapsed refractory metastatic breast cancer (**TNBC or ER+/Her2-**)
- ECOG 0-2
- At least one measurable lesion per RECIST 1.1
- Must have progressed through at least 2 lines of therapy and for whom there are no available therapies that confer a clinical benefit

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 Lopez
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
- **Close to accrual, call research coordinator to confirm slot**

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), Vismodegic (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

Genentech (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: Tate Closson-Niese

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: Tate Closson-Niese

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: Kristen Califano

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

19-0556A Randomized Phase II Study of Anti-PD-1 and Limited Metastatic Site Radiation Therapy Versus Anti-PD-1 Alone for Patients With Microsatellite Instability-high (MSI-H) and Mismatch Repair Deficient (dMMR) Metastatic Solid Tumors (NCT04001101) PI: Christine Fisher

- ECOG 0 or 1
- Unresectable or metastatic MSI-H/dMMR tumors eligible to receive pembrolizumab according to FDA-approved indications:
- Solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options
- Confirmation from medical or gynecologic oncology that the patient is eligible to receive pembrolizumab per FDA-approved indication.
- At least one site of disease amenable to radiation therapy per the acceptable dosing regimens outlined in section 6.2, and at least one additional site of measurable disease suitable for out-of-field response assessment.
- Cannot have active collagen vascular disease (CVD), specifically systemic lupus erythematosus or scleroderma. Patients with a history of CVD without evidence of active disease are eligible for enrollment at the discretion of the study PI.
- Cannot have had prior treatment with immune checkpoint inhibitor

Stage I-III Breast Cancer Clinical Trials

A. Multiple subtypes

a. Newly Diagnosed/No prior treatment

18-2444 Tracking the Natural History of Facial Skin Health in Pre and Peri Menopausal Breast Cancer Patients Undergoing Chemotherapy and / or Endocrine Therapies: A Feasibility Study (NCT04035408)

PI: Lisa Corbin, Study Coordinator: Hannah Meyer

- Stated willingness to comply with all study procedures and be available for the duration of the study
- Be a pre or perimenopausal woman age 18 or over
- Be a patient with a new diagnosis of breast cancer who plans to undergo systemic chemotherapy or endocrine therapy, but who has not yet started treatment

Exclusion Criteria:

- Postmenopausal status (one year without a menstrual period)
- Pregnant women (pregnancy test not required)

- Prior cancer diagnosis of any type other than breast cancer
- History of prior treatment with chemotherapy or radiation therapy
- Chronic skin disease including scleroderma, discoid lupus, atopic dermatitis, rosacea, ezema, or psoriasis
- Use of a retinoid-based prescription facial skin product within the past 11 months

b. Adjuvant

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: 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)

- 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 (6Co-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

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 $\geq 30\%$
- Male or female
- N3 excluded

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: Stephanie Armstead
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

19-0206 A Phase I, Multicenter, Open-Label Preoperative, Short-Term Window Study of GDC-9545 in Postmenopausal Women With Stage I-III Operable, Estrogen Receptor-Positive Breast Cancer
(NCT03916744) PI: Peter Kabos, Study Coordinator: Kari Corby

- Must be ER+/HER2-
- No prior tx (surgical, hormonal, radiotherapy)
- Stage I-III, eligible for primary surgery. Tumor must be ≥ 1.5 cm
- Post-menopausal Females only
- ECOG 0-1
- Central tissue testing required
- No concurrent use of hormone replacement therapy
- No distant mets
- No previous systemic or local treatment for primary breast cancer under investigation

b. Adjuvant

18-2357 A Phase III Multi-center, Randomized, Open-label Trial to Evaluate Efficacy and Safety of Ribociclib With Endocrine Therapy as an Adjuvant Treatment in Patients With Hormone Receptor-positive, HER2-negative Early Breast Cancer (New Adjuvant Trial With Ribociclib [LEE011]: NATALEE)
(NCT03701334) PI: Shagisultanova, Study Coordinator: Heather Nelson

- Her2- and HR+
- Must be within 18 months of diagnosis
- Surgical margins negative, stage II/III
- ECOG 0-1
- No AI's within 2 years
- No prior CDK 4/6 inhibitor

c. Other/DCIS

19-0632 A Large-scale Multicenter Phase II Study Evaluating the Protective Effect of a Tissue Selective Estrogen Complex (TSEC) in Women With Newly Diagnosed Ductal Carcinoma in Situ (The PROMISE Study, Duavee in Women with DCIS)
(NCT02694809) PI: Gretchen Ahrendt, Study Coordinator: Leah Adams

- ER+ DCIS scheduled to undergo surgery, DCIS must be ≥ 1 cm on ultrasound or MRI, ≥ 5 mm on one single core, or ≤ 5 mm if on multiple cores
- Postmenopausal
- ECOG 0-2
- No current HRT, SERM or AI therapy (30 day washout)
- No recurrent ipsilateral DCIS

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 ≥ 1 cm 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

19-0476 TAILOR RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer (NCT03488693) PI: Rabinovitch Study

Coordinator:

- ER+ and Her2-
- Must be >40 years old
- Must have had a mastectomy or breast conserving surgery with 1-3 positive axillary nodes
- Must have oncotype Dx score of <18
- Must plan endocrine therapy for >5 years

18-0627 Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation With Breast Reconstruction

(NCT03414970) PI: Rabinovitch, Study Coordinator: Chelsea Schaefer

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
Anosheh Afghahi, MD	Anschutz	720-848-9302	Anosheh.Afghahi@ucdenver.edu

Virginia Borges, MD	Anschutz & Lone Tree	720-848-9302	Virginia.Borges@ucdenver.edu
Regina Brown, MD	Lone Tree	720-848-9302	Regina.Brown@ucdenver.edu
Jennifer Diamond, MD	Anschutz	720-848-9302	Jennifer.Diamond@ucdenver.edu
Anthony Elias, MD	Anschutz	720-848-9302	Anthony.Elias@ucdenver.edu
Christine Fisher, MD – Radiation	Anschutz	720-848-9302	Christine.Fisher@ucdenver.edu
Peter Kabos, MD	Anschutz	720-848-9302	Peter.Kabos@ucdenver.edu
Jose Mayordomo, MD	Anschutz	720-848-9302	Jose.Mayordomo@ucdenver.edu
Sameer Nath, MD - Radiation	Anschutz	720-848-9302	Sameer.Nath@ucdenver.edu
Rachel Rabinovitch, MD - Radiation	Anschutz	720-848-9302	Rachel.Rabinovitch@ucdenver.edu
William Robinson, MD	Anschutz	720-848-9302	William.Robinson@ucdenver.edu
Elena Shagisultanova, MD	Anschutz	720-848-9302	Elena.Shagisultanova@ucdenver.edu
Melony Avella-Howell, NP	Anschutz - GI/Phase I	720-848-9302	Melony.Avella-Howell@ucdenver.edu
Colleen Dougherty-Gray, NP	Anschutz	720-848-9302	Colleen.Dougherty-Gray@ucdenver.edu
Laurri Jones, NP	Anschutz	720-848-9302	Laurri.Jones@ucdenver.edu
Breast CRCs	Office	Pager	Email
Melanie Schwartz– Clinical Operations Manager	720-848-0653		Melanie.f.Schwartz@cuanschutz.edu
Swing, Robyn- – Project Manager	720-848-0607		Robyn.Swing@cuanschutz.edu
Adams, Leah	720-848-7341		Leah.Adams@cuanschutz.edu
Armstead, Stephanie	720-848-0729	303-266-4520	Stephanie.Armstead@ucdenver.edu
Corby, Kari	720-848-0675	303-266-1038	Kari.Corby@ucdenver.edu
Lopez, Kyrie	720-848-9456	303-266-4695	Kyrie.Lopez@cuanschutz.edu

Lopez, Lisa—Lone Tree	720-553-1133	303-266-2589	Lisa.Lopez@ucdenver.edu
Nelson, Heather	720-848-9351	303-266-4314	Heather.L.Nelson@ucdenver.edu
Belford, Melissa	720-848-8031	303-266-0428	Melissa.Belford@cuanschutz.edu
Breast CRC On Call		303-266-6404	
Meyer, Heather (CreST)			Hannah.M.Meyer@Cuanschutz.Edu
Molecular Oncology CRCs	Office	Pager	Email
Morgan, Zackry – Supervisor Molecular Oncology	720-848-	303-266-	Zackry.morgan@cuanschutz.edu
Closson-Niese, Tate	720-848-0669	303-266-1829	Tate.Closson-Niese@ucdenver.edu
Collins, Siobhan	720-848-0660	303-266-0804	Siobhan.Collins@cuanschutz.edu
Mason, Chelsea	720-848-0289	303-266-1277	Chelsea.Mason@cuanschutz.edu
Morgan, Zackry	720-848-5494	303-266-4726	Zackry.Morgan@cuanschutz.edu
Martinez, Flora, RN	720-848-5202	303-266-5212	Flora.Martinez@ucdenver.edu
Phase I CRCs	Office	Pager	Email
Lark, Amanda	720-848-0678		Amanda.Lark@ucdenver.edu
Siedem, Amanda	720-848-0052	303-266-1442	Amanda.Siedem@ucdenver.edu
Freas, Elizabeth	303-724-8632	303-266-2328	Elizabeth.Freas@ucdenver.edu
Califano, Kristen	720-848-0592		Kristen.Califano@cuanschutz.edu
Rippke, Sarah	720-848-0685	303-266-1710	Sarah.Rippke@ucdenver.edu
Wells, Tara RN	720-848-0755	303-266-1654	Tara.Wells@ucdenver.edu
Neu, Sheri RN	720-848-0691	303-266-4241	Sheri.Neu@ucdenver.edu
Phase I On Call		303-266-2328	
Radiation CRCs	Office	Pager	Email
Swing, Robyn – Manager	720-848-0607	303-266-7223	Robyn.Swing@ucdenver.edu
Withrow, Suzanne – Supervisor	720-848-0593	303-266-6227	Suzanne.Withrow@ucdenver.edu
Schaefer, Chelsea	720-848-0608	303-266-3662	Chelsea.Schaefer@ucdenver.edu