

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:

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

Updated: July 1, 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: Peter Kabos, Study Coordinator: Stephanie Armstead

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

Lone Tree Medical Center

- 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 month)

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

- **Parts D & E enrolling**
- 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

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

- 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: Peter Kabos, Study Coordinator: Kyrie Lopez

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

- **PART B & C open**
- 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

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

- 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

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

Lone Tree Medical Center

Highlands Ranch Hospital

- 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 (Afghahi, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Medical Center

Highlands Ranch Hospital

- 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

b. Second Line and beyond

19-1977 is a 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 (NCT03975647) PI: Virginia Borges, Study Coordinator: Leah Adams
Breast Cancer Research Team Anschutz (Afghahi, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- HER2+ metastatic breast cancer in women or men (ER status must be known prior to randomization)
- Prior treatment with a taxane and trastuzumab in any setting, separately or in combination. Prior pertuzumab therapy is allowed, but not required
- Can have brain mets, but must meet CNS inclusion criteria in protocol
- No prior treatment with tucatinib, neratinib, afatinib, trastuzumab deruxtecan (DS-8201a), or any other investigational anti-HER2, anti-EGFR, or HER2 TKI agent
- No prior treatment with T-DM1

C. TNBC

a. First Line

19-1337 A Phase 2, Multi-arm, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of IPI-549 Administered in Combination With Nab-paclitaxel +/- Atezolizumab in Patients With Locally Advanced and/or Metastatic Triple-Negative Breast Cancer or Renal Cell Carcinoma

(NCT03961698) PI: Elias, Study Coordinator: Kari Corby

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

Lone Tree Medical Center

- Measureable disease
- Willing to undergo biopsies
- ECOG status ≤ 1
- Cohort A –
 - Women with metastatic or locally advanced TNBC
 - No prior chemotherapy or targeted systemic therapy for inoperable locally advanced or metastatic TNBC
 - Prior chemotherapy in the neoadjuvant or adjuvant setting is allowable if treatment was completed ≥ 12 months prior to randomization
- No history of, or currently active, brain or leptomeningeal metastases

b. Second or Third Line

18-1933 A Phase II, Open Label, Randomized, Multi-center 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

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

Lone TreeMedical Center

- **Stratum C closed and AZD1775 arm discontinued**
- **Stratum A & B open**
- 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 (Afghahi, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Part 2, Cohort 1: TNBC

- Histologically confirmed metastatic TNBC
- 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
- ECOG PS of ≤ 2
- Able to provide an archival tumor tissue sample

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

- Metastatic breast carcinoma with previous clinical diagnosis of IBC
- Received at least one prior line of systemic chemotherapy in the metastatic setting.
- No taxane within 6 months
- ECOG PS of ≤ 2
- Able to provide an archival tumor tissue sample

d. Later Line

18-0685 A Phase 1/2 Dose Escalation and Dose Expansion Study of BA3021 (CAB-ROR2-ADC) in Patients With Advanced Solid Tumors

(NCT03504488) PI: Anthony Elias, Study Coordinator: Tate Closson-Niese
Anschutz Phase I, Expansion and Molecular Studies (Elias, Mayordomo, Kabos, Diamond)

- Prescreening consent for ROR2 expression to determine if eligible.
- Must have measurable disease
- Dose expansion phase: Patients with locally advanced unresectable or metastatic TNBC
- No prior treatment with conjugated or unconjugated auristatin derivative/vinca-binding site targeting payload
- ECOG 0-1

e. Any Line

Accrual On-Hold

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 (Afghahi, 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

19-0539 A Multi-Center, Open-Label, Phase 1/1b Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Anticancer Activity of Fruquintinib in Patients with Advanced Solid Tumors (NCT03251378) PI: Christopher Lieu, Study Coordinator: Meredith Waring

Anschutz Phase I, Expansion and Molecular Studies (Elias, Mayordomo, Kabos, Diamond)

- I. *Expansion Cohort D:* ER+ and/or PR+/Her2- mBC who have progressed on at least two lines of prior systemic therapy
 - Patients may not have received more than 3 prior lines of cytotoxic chemotherapy in metastatic setting. There is no limit to number of prior lines of hormonal therapy.
- II. *Expansion Cohort E:* Advanced TNBC who have progressed on at least one cytotoxic therapy in the metastatic setting

- Must have progressed on at least 1 cytotoxic therapy in the metastatic setting, with the exception of subjects who progressed within 12 months of adjuvant therapy. However, patients may not have received more than 5 prior lines of cytotoxic chemotherapy in the metastatic setting.
- Have measurable disease per RECIST Version 1.1, or bone lesions in the absence of measurable disease
- (ECOG) performance status of 0 or 1
- Cannot have a history of a thromboembolic event (including deep vein thrombosis [DVT], pulmonary embolism, stroke and/or transient ischemic attack) within 6 months prior to screening
- No prior VEGFR inhibitor **except** for patients with mCRC enrolled in the dose expansion phase

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

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

- 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
- **Waitlist – contact CTC for 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

Anschutz Phase I, Expansion and Molecular Studies (Elias, Mayordomo, Kabos, Diamond)

- 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

Anschutz Phase I, Expansion and Molecular Studies (Elias, Mayordomo, Kabos, Diamond)

- 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

Anschutz Phase I, Expansion and Molecular Studies (Elias, Mayordomo, Kabos, Diamond)

- 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: Andy Coy

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

19-0556 A 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, Study Coordinator: Jillian Welker

- 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, eczema, or psoriasis
- Use of a retinoid-based prescription facial skin product within the past 11 months

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: Melissa Belford

Breast Cancer Research Team Anschutz (Afghahi, 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

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 (Afghahi, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team

Breast Cancer Research Team North

Highlands Ranch Hospital

- 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 (Afghahi, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

Breast Cancer Research Team North

Breast Cancer Research Team South

Highlands Ranch Hospital

- 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: Kyrie Lopez

- 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 (Afghahi, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Medical Center

- 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 (Afghahi, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

Highlands Ranch Hospital

- 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

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

Lone Tree Medical Center

- Must be ER+/HER2-
- No prior tx (surgical, hormonal, radiotherapy)
- Stage I-III, eligible for primary surgery. Tumor must be \geq 1.5cm
- 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. 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

Breast Cancer Research Team Anschutz

Lone Tree Medical Center

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

19-1602 A Prospective Registry Study to Evaluate the Effect of the DCISionRT Test on Treatment Decisions in Patients With DCIS Following Breast Conserving Therapy (NCT03448926) PI: Rachel Rabinovitch

- Histologically confirmed DCIS in a single breast
- Must have DCISionRT™ Test ordered during routine patient care
- Must be planning to undergo breast conserving surgery
- Must be eligible to receive radiation and/or systemic treatment
- Must have been diagnosed with DCIS within 120 days of consent

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 \geq 1cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy

(NCT02954874) PI: Elias, Study Coordinator: Stephanie Armstead

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

Lone Tree Research Team

Highlands Ranch Hospital

Breast Cancer Research Team North

Breast Cancer Research Team South

- 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 Lone Tree	720-848-9302	Anosheh.Afghahi@cuanschutz.edu
Virginia Borges, MD	Anschutz Lone Tree	720-848-9302	Virginia.Borges@cuanschutz.edu
Jennifer Diamond, MD	Anschutz	720-848-9302	Jennifer.Diamond@cuanschutz.edu
Anthony Elias, MD	Anschutz	720-848-9302	Anthony.Elias@cuanschutz.edu
Christine Fisher, MD – Radiation	Anschutz	720-848-9302	Christine.Fisher@cuanschutz.edu
Peter Kabos, MD	Anschutz	720-848-9302	Peter.Kabos@cuanschutz.edu
Jose Mayordomo, MD	Anschutz Highlands Ranch	720-848-9302	Jose.Mayordomo@cuanschutz.edu
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