

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>

Updated: November 1, 2019

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
- Close to accrual, call research coordinator to confirm slot

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)
- Close to accrual, call research coordinator to confirm slot

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

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

C. TNBC

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)

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 tumour 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

19-1111 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

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: Melissa Belford

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 (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

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 (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. 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

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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