Stem a	Neoadjuvant	Adjuvant	Metastatic	Brain Mets
HR+, HER2 -	**TBCRC-059/ETHAN: Y. Abdou/Emily Schworer** A phase II study comparing different Endocrine Therapies for Male breast cancer **Brief Eligibility: Inclusion** • **Men** 18 y.o or older, w/ invasive breast cancer who have not undergone surgical resection. • Stage I, II, or III • ER >1%, or PR> 1% & HER2- (0 or 1+). • Patients with multifocal or multicentric disease are eligible if the treating investigator has determined the patient should be treated as ER-positive and HER2-negative. **Exclusion:** • Prior anti-cancer therapy • Inflammatory Breast Cancer	**A191901/GETSET (Mireille Leone/KRH)** Optimizing Endocrine Therapy Adherence through motivational interviewing and text Intervention. opening in early March. ONLY ACCRUING BLACK +/- 65 YR OLD WOMEN and must be starting ET or have started ET within the last six months. **LCCC2104- CAMERAN (Cory Greenwood/Casey)** low risk localized ER+ breast cancer randomizing to either partial breast irradiation vs endocrine therapy **NRG-BR009(Taylor Pierce/Dees):** Ph III Adjuvant Trial Evaluating the Addition of Adj Chemo to OFS + Endocrine Therapy in Premenopausal Pts w/ pN0-1, ER+/HER2-Neg Breast Cancer & an Oncotype Score ≤ 25 (OFSET) **Brief Eligibility: Inclusion** • Premenopausal patients with resected T1-3, N0-1, M0 Breast Cancer • ER and/or PR positive & HER2 negative • pN0 RS 16-20 plus high clinical risk* or RS 21-25 • pN1 with RS 0-25 **Exclusion:** • pT4 tumors, including inflam breast cancer. • Hx of ipsilateral or contralateral invasive breast cancer. • Life expectancy of < 10 years due to co-morbid conditions in the opinion of the investigator	**SCCC03121/UTSW CD40 HR+ Cohort OPEN** **Ana Gallegos/Yara Abdou** Ph 1 pilot study w/ dose expansion of chemo in combination with CD40 agonist and Flt3 ligand in Her2 negative met breast cancer **HR+, Her2 negative** • ER or PR ≥10% and HER2- negative or • Received up to 3 prior lines of chemo and/or ADC for met dz **Triple Negative** • Life expectancy ≥ 12 weeks • ER <10%, PR <10%, and HER2- negative • PD-L1 negative by 22C3 assay & not eligible for SOC chemo & anti-PD-1/PD-L1 combo therapy • Subject is in first to 4th line setting of treatment for mets • Must have received prior cyclin dependent kinase inhibitor **DB1303-O-3002:(Dees/Emily Schworer)** Phase 3, Randomized, Open-label Study of DB-1303 Vs Investigator's Choice Chemotherapy in (HER2)-low, (HR+) Met. Breast Cancer who has progressed on ET. **Inclusion**: • HER2-low (1+ or 2+) by the central lab, Never reported as HER2 pos • HR+ (ER or PR ≥1%). • Must have had either: ○ 1) Disease prog on ET + CDK4/6 inh. within 6 mo of starting 1st line tx OR ○ 2) Disease prog on at least 2 previous lines of ET w/or without a targeted therapy **Exclusion:** • Ineligible for all options in the investigator's choice arm. • Clinically uncontrolled pleural effusion, ascites or pericardial effusion requiring repeated drainage	**BRE 18-360 (Camisha Johnson/Shen)** Phase I/II Study Stereotactic Radiosurgery with Concurrent Administration (Olaparib) Followed by Adjuvant Combination of Durvalumab and Physician Choice Systemic Therapy • HER2-negative with germline or somatic BRCA mutation) • New dx of brain metastasis by MRI, amenable to stereotactic radiosurgery (SRS) (up to 10 metastases with total brain metastases volume ≤15cc). • permitted to have undergone recent craniotomy and resection of mets if at least 1 other intact metastasis planned for definitive SRS is present. • Discrete dural lesions are allowed. **A071701: (Amalia Postier/Rauf)** Genetic testing in guiding treatment; ER/PR+ must have at least one prior endocrine therapy in metastatic setting; abemaciclib, entrectinib, GDC-0084 **TAPUR- (Patel/Olivia Gorman):** - treatment assigned based on molecular profiling. Patient with a histologically proven locally advanced or metastatic solid tumor, who is no longer benefiting from standard anti-cancer treatment.

	NOT YET OPEN (below): **LCCC2425:** **(Zev Nakamura/Ashley Hanson)** **Memantine and exercise to improve cognitive function and modulate biological pathways of cognitive decline during chemotherapy in breast cancer** **Eligibility criteria:** **Inclusion:** • **-Women, >/= 50 years old** • **-Stage I-III** • **-Completed 1-2 cycles of chemotherapy** • **-Self-reporting at least mild cognitive concerns** **Exclusion:** • **-Prior cancer-directed systemic therapy**	**NOT YET OPEN (below):** **LCCC2425:** **(Zev Nakamura/Ashley Hanson)** **Memantine and exercise to improve cognitive function and modulate biological pathways of cognitive decline during chemotherapy in breast cancer** **Eligibility criteria:** **Inclusion:** • **-Women, >/= 50 years old** • **-Stage I-III** • **-Completed 1-2 cycles of chemotherapy** • **-Self-reporting at least mild cognitive concerns** **Exclusion:** • **-Prior cancer-directed systemic therapy**	**NOT YET OPEN (below):** **PUMA-ALI-1201: (Dees/Emily Schworer)** A Phase 2 Study of Alisertib in Combination with Endocrine Therapy in Patients with HR+, HER2-Negative Recurrent or Metastatic Breast Cancer	**Brief Eligibility: Inclusion** • Results must be available from a genomic test or immunohistochemistry (IHC) test for protein expression • Measurable disease by physical exam or by RECIST 1.1 • No steroids in the past months • Brain Mets are eligible but must be stable and not requiring treatment. No seizures in the last 14 days.

HER2+	**NOT YET OPEN (below):** **LCCC2425:** **(Zev Nakamura/Ashley Hanson)** **Memantine and exercise to improve cognitive function and modulate biological pathways of cognitive decline during chemotherapy in breast cancer** **Eligibility criteria:** **Inclusion:** • **-Women, >/= 50 years old** • **-Stage I-III** • **-Completed 1-2 cycles of chemotherapy** • **-Self-reporting at least mild cognitive concerns** **Exclusion:** • **-Prior cancer-directed systemic therapy**	**A011801-(Taylor Pierce/Carey):** COMPASHER2-RD: double-Blinded, Randomized Trial of T-DM1 vs T-DM1 and Tucatinib **Brief Eligibility: Inclusion** • Must be Her2 positive • clinical T1-4, N0-3 disease at presentation. • Residual HR neg, HER2+ disease in the breast or lymph nodes per surg path • HR+, HER2+ disease must have disease in their lymph nodes **Exclusion Criteria** • metastatic disease **ADEPT (Taylor Pierce/Carey)** Adjuvant ET, subQ Pertuzumab, and Trastuzumab fixed-dose combination **Brief Eligibility: Inclusion** • HER2-positive T1, (N0) or (N1mi). • a. If negative sentinel node biopsy, then no further axillary dissection is required, & the patient is determined to be N0. b. Axillary LN w/ tumor clusters between 0.02 & 0.2cm is considered a micromet & are eligible. c. Patients T1aN0, ER+ (defined as >10%), HER2-negative cancer in either breast, in addition to their primary HER2 positive tumor, are eligible. **Exclusion:** • Neoadjuvant or adjuvant chemotherapy for this breast cancer prior to enrollment is prohibited. • Locally advanced tumors at diagnosis, including tumors fixed to the chest wall, peau d'orange, skin ulcerations/nodules, or clinical inflammatory changes (diffuse brawny cutaneous induration with an erysipeloid edge)	**NOT YET OPEN (below):**	**A071701** **(Camisha Johnson/Rauf)** Genetic testing in guiding treatment; HER2+, received prior HER2 directed therapy in metastatic settting; abemaciclib, entrectinib, GDC-0084 **TAPUR- (Patel/Olivia Gorman):** - treatment assigned based on molecular profiling. Patient with a histologically proven locally advanced or metastatic solid tumor, who is no longer benefitting from standard anti-cancer treatment. **Brief Eligibility: Inclusion** • Results must be available from a genomic test or immunohistochemistry (IHC) test for protein expression • Measurable disease by physical exam or by RECIST 1.1 • No steroids in the past months • Brain Mets are eligible but must be stable and not requiring treatment. No seizures in the last 14 day **NOT YET OPEN (below):**

TNBC

NOT YET OPEN (below):
(Abdou, Ana Gallegos)
Scarlet S2212: Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study

LCCC2425:
(Zev Nakamura/Ashley Hanson)
Memantine and exercise to improve cognitive function and modulate biological pathways of cognitive decline during chemotherapy in breast cancer
Eligibility criteria:
Inclusion:
- **-Women, >/= 50 years old**
- **-Stage I-III**
- **-Completed 1-2 cycles of chemotherapy**
- **-Self-reporting at least mild cognitive concerns**

Exclusion:
- **-Prior cancer-directed systemic therapy**

A012103 OptimICE-PCR (Emily Schworer/Abdou)

De-escalation of therapy in early-stage TNBC patients who achieve PCR after neoadjuvant chemotherapy with checkpoint inhibitor
- StageT1CN1-2 OR T2-4N0-2
- Must have no residual disease
- ER/PR <10%, HER2 negative
- Must have received neo-adjuvant chemotherapy with pembro for 6 cycles

ASCENT-05/GS-US-595-6184/AFT-65- (Taylor Pierce/Abdou)

Phase 3 Study of Adj. Sacituzumab Govitecan and Pembro Vs Treatment of Physician's Choice in Patients With TNBC Who Have Residual Invasive Disease After Surgery & Neoadjuvant Therapy

Brief Eligibility: Inclusion
- Patients must have a history of clinical stage T1, N1-2 or T2-4, N0-2 and histologically confirmed TNBC as determined by the investigator with residual disease in the breast or lymph node(s) after completion of neoadjuvant therapy and surgery.
- Additionally, the presence of distant metastatic disease must be ruled out.
- ER and PgR < 10%, HER2-negative per ASCO/CAP guidelines

DF-HCC-20-166 (Emily Schworer-Abdou)

Sacituzumab +/- pembro

Brief Eligibility: Inclusion
- Treatment naïve TNBC, PDL-1 negative
- Previously treated brain mets are permitted
- Research bx at SCR & C2 if safely accessible

Exclusion Criteria
- Prior tx with any anti-PD-1, PD-L1, or PD-L2 agent or saci
- Prior tx with irinotecan or topoisomerase I-containing ADC
- Inflammatory (cT4d) breast cancer
- Known brain mets that are untreated, symptomatic, or require therapy

TBCRC047/BCRF (Emily Schworer/Abdou)

Immunotherapy in TNBC with Hope Rugo

Brief Eligibility: Inclusion
- ER/PR-negative (≤ 5% cells) & HER2 neg
- Known tumor/immune cell PD-L1 status

Exclusion Criteria
- More than 2 prior lines of chemo
- > than 1 prior line of checkpoint inh
- Prior Sacituzumab govitecan
- Use of immunosuppressants and corticosteroids

LCCC2128-Catherine Cheng/Dees

Phase I Study of Administration of T Cells Expressing B7-H3 Specific Chimeric Antigen Receptors (CAR)

Brief Eligibility: Inclusion
- ER-, PR- (<1%), HER2 negative
- Stable brain mets allowed
- Must have progressed on at least 1 line of therapy in mets setting

DF/HCC 20-166 (Emily Schworer/Carey)

Sacituzumab +/- pembro

Brief Eligibility: Inclusion
- Treatment naïve TNBC
- PDL-1 negative
- Previously treated brain mets are permitted with exceptions
- Must undergo a research bx at screening and C2 if safely accessible

Exclusion Criteria
- Prior tx with any anti-PD-1, PD-L1, or PD-L2 agent or sacituzumab govit.
- Prior tx with irinotecan or topoisomerase I-containing antibody drug conjugates at any time
- Known brain metastases that are untreated, symptomatic, or require therapy to control symptom

BRE 18-360 (Camisha Johnson/Shen)

Phase I/II Study Stereotactic Radiosurgery with Concurrent Administration (Olaparib) Followed by Adjuvant Combination of Durvalumab and Physician Choice Systemic Therapy
- HER2-negative with germline or somatic BRCA mutation)
- New dx of brain metastasis by MRI, amenable to stereotactic radiosurgery (SRS) (up to 10 metastases with total brain metastases volume ≤15cc).

NOT YET OPEN (below):

LCCC2425:

(Zev Nakamura/Ashley Hanson)

Memantine and exercise to improve cognitive function and modulate biological pathways of cognitive decline during chemotherapy in breast cancer

Eligibility criteria:

Inclusion:

- **-Women, >/= 50 years old**
- **-Stage I-III**
- **-Completed 1-2 cycles of chemotherapy**
- **-Self-reporting at least mild cognitive concerns**

Exclusion:

- **-Prior cancer-directed systemic therapy**

NBTX-1100 (Stephanie Corbett/Shen)

- NBTXR3 Activated By Radiotherapy for Patients with Advanced Cancers Treated With an Anti-PD1 Therapy.
- Therapy: NBTXR3 + RT + Anti-PD1 (Pembrolizumab or Nivolumab)
- Patient will receive one intratumoral injection of NBTXR3 followed by 3 to 5 fractions of RT and then Anti-PD1
- TNBC w/ mets to soft tissues, lung, or liver

NX-1607-101 (Weiss/Melissa Flores)

A Phase 1a, Study of NX-1607, a CBL-B inhibitor, in Adults w/ Adv. Malignancies, with Phase 1b Expansion in Select Tumor Types

Brief Eligibility: Inclusion

- Patients w/ deleterious or suspected deleterious gBRCAm, HER2-neg met TNBC cancer must have received PARP-inhibitor.
- Patients with unresectable locally advanced or metastatic TNBC who received ≥ 2 prior therapies for metastatic disease.

1042-CLN01- (Sheth, Olivia Gorman)

Ph 1 of ICVB-1042 in Pts w/ Adv Solid Tumors

Brief Eligibility: Inclusion

- Progression on or after 1 prior line
- Measurable disease

Exclusion Criteria

- CNS and leptomeningeal disease
- Supplemental O2 requirement
- Cardiac abn (MI, prolonged QTC)
- permitted to have undergone recent craniotomy and resection of mets if at least 1 other intact metastasis planned for definitive SRS is present.
- Discrete dural lesions are allowed.

A071701

(Camisha Johnson/Rauf)

Genetic testing in guiding treatment; TNBC, one prior chemotherapy in metastatic setting; abemaciclib, entrectinib, GDC-0084

TAPUR- (Patel/Olivia Gorman):

- treatment assigned based on molecular profiling. Patient with a histologically proven locally advanced or metastatic solid tumor, who is no longer benefitting from standard anti-cancer treatment.

Brief Eligibility: Inclusion

- Results must be available from a genomic test or immunohistochemistry (IHC) test for protein expression
- Measurable disease by physical exam or by RECIST 1.1
- No steroids in the past months
- Brain Mets are eligible but must be stable and not requiring treatment. No seizures in the last 14 days.

			SCCC03121/UTSW CD40 **Ana Gallegos/Yara Abdou** Phase 1 pilot study with dose expansion of chemotherapy in combination with CD40 agonist and Flt3 ligand in metastatic triple negative breast cancer • Unresectable Stage III or Stage IV TNBC • ER <10%, PR<10% and HER2- (0 or 1+) • Life expectancy ≥ 12 weeks • For initial safety cohort, subject is in 2nd to 3rd line setting of tx for metastatic or unresectable disease & have received 1-2 prior regimens for metastatic disease. • For dose expansion, the subject is in 1st-3rd line setting of treatment and have received 0 to 2 prior regimens for metastatic or unresectable disease. • Any patient enrolled in the 1st line setting, subjects must be PD-L1 neg & not be eligible for SOC chemotherapy and anti-PD-1/PD-L1 combination therapy as alternative to this clinical trial. **NOT YET OPEN (below):** **TBCRC-058: (Y. Abdou/Taylor Pierce)** A randomized, Phase II study of Enzalutamide, enzalutamide with mifepristone, and treatment of physicians' choice with AR+ metastatic triple negative or ER- or ER LOW breast cancer **ProDA/Emory: Abdou/Tamara Pfeffer** Phase I/II Trial Evaluating the Safety and Efficacy of ProAgio, an anti- αvβ3 Integrin Cytotoxin, in Combination with Gemcitabine in Patients with Metastatic Triple Negative Breast Cancer	

Phase I

APL-101-01 ***(Olivia Gorman/Dees)*** : Phase 1 / 2 Multicenter Study of the Safety, Pharmacokinetics, and Preliminary Efficacy of APL-101 in Subjects with Non-Small Cell Lung Cancer with c-Met EXON 14 Skip Mutations and c-Met Dysregulation Advanced Solid Tumors (7 cohorts) **Brief Eligibility: Inclusion;** C-met mutation required

TAPUR- (Olivia Gorman/Patel): - treatment assigned based on molecular profiling. Patient with a histologically proven locally advanced or metastatic solid tumor, who is no longer benefitting from standard anti-cancer treatment. **Available Open Cohorts:** https://cdn.bfldr.com/KOIHB2Q3/as/39tsg65qhf362fx5fqfskp/2025-Jan-TAPUR-Cohort-Report

Brief Eligibility: Inclusion

- Results must be available from a genomic test or immunohistochemistry (IHC) test for protein expression
- Measurable disease by physical exam or by RECIST 1.1
- Brain Mets are eligible but must be stable and not require treatment. No seizures in the last 14 days.

NX-1607-101 (Weiss/Melissa Flores)- Not enrolling on the current arm

A Phase 1a, Dose Escalation, Safety and Tolerability Study of NX-1607, a Casitas B-lineage lymphoma proto-oncogene (CBL-B) inhibitor, in Adults with Advanced Malignancies, with Phase 1b Expansion in Select Tumor Types

Brief Eligibility: Inclusion

- Patients with unresectable locally advanced or metastatic TNBC who received ≥ 2 prior therapies for metastatic disease.
- Patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic TNBC cancer must have received treatment that included a PARP-inhibitor.

NCI-10486 (Patel/Melissa Flores)

Phase 2 Trial of the Combination of the BET inhibitor, ZEN003694 (ZEN-3694), and the PARP Inhibitor Talazoparib, in Patients with Molecularly-Selected Solid Tumors (ComBET)

Brief Eligibility: Inclusion

- confirmed malignancy that is metastatic or unresectable
- must have a tumor lesion that can be biopsied with 'low' or 'minimal' risk and at least one measurable disease site, as defined by RECIST v1.1.
- Patients must have received at least one line of systemic therapy in the advanced/metastatic setting.
- ECOG performance status ≤2

Mirati 849-001 (Weiss/Olivia Gorman)-Phase 1/2 of MRTX849 a KRAS G12C Mutation targeting agent for Advanced Solid Tumors

Brief Eligibility:

- Must have histologically confirmed diagnosis of a solid tumor malignancy with KRAS G12C mutation
- Must have unresectable or metastatic disease
- Must not be a candidate for standard treatment or patient declines standard treatment; first-line treatment for NSCLC for certain cohorts
- No history of intestinal disease or major gastric surgery or inability to swallow oral medications

1042-CLN01- Ph. 1 First-in-Human Dose Escalation & Expansion Study to Assess Safety & Tolerability of IV Administration of ICVB-1042 in Patients w/ Adv. Solid Tumors (Olivia Gorman/Sheth) Not enrolling on the current arm

- Histological or cytologically confirmed solid tumor malignancy that is locally advanced or metastatic.
- Progression on or after at least one prior standard of care (SOC) therapy including immune checkpoint inhibitors and therapies

Surg	• **PET-MR** *(David/Lalush/Gallagher)* NA patients PET-MR pre- and post-tx • **TBCRC-042** *(Gallegos/Gallagher)* Window trial for DCIS, LCIS, ADH, and ALH with ruxolitinib
TSHS/RAMSES	• **Tumor Donation/ Rapid Autopsy** *(Stem/Carey)* Entering Hospice or rapid disease progression/decline • **LCCC9819:** *(Mireille Leone/Carey)*- consider during metastatic biopsies, collects at all procedures; early stage and metastatic • **HARMONY1829**:*(Eubanks/Carey)* PAM50/RNA sequencing for 1st line met pts, no later than 1st line • **AURORA***: (Stem/Carey)* Prospective Biospecimen Repository in Metastatic Breast Cancer; **Paused to new accruals, patients already enrolled can consent to a serial biopsy tissue collection of a distant metastatic site.** • **A191901/GETSET (Mireille Leone/KRH) – Optimizing ET Adherence through Motivational Interviewing and Text Intervention – REOPENED**. ONLY ACCRUING BLACK +/- 65 YR OLD WOMEN and must be starting ET or have started ET within the last six months. • **LCCC 2226 EASINESS** (Stem/Carey): scheduled to receive treatment with an antibody-drug conjugate (ADC) and have tissue available from a previous or upcoming pre-tx metastatic biopsy • **CareTracker (Kacee Little/KRH):** Using Patient-Reported Data to Address Racial Disparity in Cancer Treatment. Early stage breast or colorectal cancer, dx within 6 weeks of enrollment. • **POEM (Kacee Little/KRH):** Patient Outcomes and Experiences in Metastatic Breast Cancer. MBC dx with distant met, English speaking, treated at UNC. • **PRISM (Kacee Little/KRH):** Promoting Resilience in Women With Breast Cancer.
Neuro	**BRE 18-360 (Johnson /Shen)** Phase I/II Study Stereotactic Radiosurgery with Concurrent Administration (Olaparib) Followed by Adjuvant Combination of Durvalumab and Physician Choice Systemic Therapy • HER2-negative with germline or somatic BRCA mutation) • New dx of brain metastasis by MRI, amenable to stereotactic radiosurgery (SRS) (up to 10 metastases with total brain metastases volume ≤15cc). • permitted to have undergone recent craniotomy and resection of mets if at least 1 other intact metastasis planned for definitive SRS is present. • Discrete dural lesions are allowed. **A071701: (Amalia Postier/Rauf)** Genetic testing in guiding treatment; ER/PR+ must have at least one prior endocrine therapy in metastatic setting; abemaciclib, entrectinib, GDC-0084
Rad Onc	**CCTG-MA-39 (Chasity McCue, Casey)** Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer • Regional Radiotherapy vs. No Regional Radiotherapy • RT must commence within 16 weeks of definitive surgery if the patient is not treated with chemotherapy. If adjuvant chemotherapy is given, RT must begin within 12 weeks after the last dose • Endocrine therapy can be given concurrently or following RT. • Patients will follow-up at 6 months, and then annually post randomization **GTM-102 (Shen, Chasity McCue)** A Phase 3 Randomized Controlled Trial of Post-Surgical Stereotactic Radiotherapy (SRT) versus Surgically Targeted Radiation Therapy (STaRT) with Gamma Tile for Treatment of Newly Diagnosed Metastatic Brain Tumors

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