Oncology Clinical Trial List
October 2023

Breast	
ER+HER2- breast cancer **Histol/cyto diagnosis of locally advanced or metastatic ER+HER2 breast cancer, must have progressed after first line (1st line depends on phase we are in)* **Documentation of ER-positive tumor (≥1% positive stained cells) based on most recent tumor biopsy* **documentation of HER2-negative tumor: determined as immunohistochemistry score 0/1+ or negative by in situ hybridization* **must be willing to undergo medically induced menopause by treatment with the approved LHRH agonist such as goserelin, leuprolide or equivalent* **at least 1 measurable lesion as defined by RECIST version 1.1 not previously irradiated.* **ECOG - PS 0 or 1* **Adequate renal, liver, and bone marrow function.* **Resolved acute effects of prior therapy to baseline severity or CTCAE Grade 1*	A Randomized, Open-label, Phase 3 Study of Adjuvant Imlunetrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endrocine Therapy for ER+, HER 2- Early Breast Cancer with an Increased Risk of Recurrence **Eli Lilly J2J-MC-JZLH** **NCT05514054** https://clinicaltrials.gov/ct2/show/NCT05514054
**Post-menopausal females ≥ 18 years* **Histologically or cytologically confirmed ER+ and HER2* **ER andHER2 status must be documented: ER+ disease, with ER staining of ≥ 10% of tumor cell nuclei by IHC per ASCO/CAP Guidelines (Allison2020).* **HER2- disease by either IHC or in situ hybridization per ASCO/CAP* **Ki-67 score ≥ 5%, analyzed locally* **Clinical T1c-T4c, N0-N2, M0 breast cancer amenable to definitive surgical resection, without bilateralbreast ductal carcinoma in situ or invasive breast cancer* **Primary tumor must be at least 1.5 cm by imaging* **ECOG performance status of 0 or 1* **Willing to have screening biopsy, on-treatment biopsy & surgical resection*	An Open-Label, Randomized, Non-Comparative Phase 2 Study of ARV-471 or anastrozole in Post-Menopausal Women with ER+ HER2- Breast Cancer in the Neoadjuvant setting **Arvinas ARV471-BC201 (TRIO048)** **NCT05549505** https://www.clinicaltrials.gov/ct2/show/NCT05549505
**Single day chemo regimen and antiemetic* **Read English* **> 3 nausea once to proceed to C2* **No Akynzeo*	Treatment of Refractory Nausea [during chemo for breast cancer] **URCC-16070 (NCORP)** **NCT03367572** https://clinicaltrials.gov/ct2/show/NCT03367572

Breast (Continued)	
**Metastatic or locally advanced breast cancer not amenable to surgery or radiotherapy.* **Currently receiving palbociclib and AI therapy in the metastatic setting with evidence of progressive disease.* **Remained on palbociclib and AI therapy for ≥6 months for advanced or metastatic breast cancer prior to evidence of progression that treating physician believes warrants continued therapy with palbociclib and AI.* **Must be continuing on palbociclib at a dose of 125, 100, or 75 mg administered orally for 21 days every 28-day cycle.* **All men and premenopausal women must be on medical gonadal suppression therapy with a gonadotropin analog (e.g, goserelin or leuprolide) and have estrogen levels in the postmenopausal range at baseline.* **ECOG of 0 or 1.* **Documented histological or cytological hormone receptor-positive (estrogen receptor-positive [ER+], human epithelial receptor 2-negative [HER2-]) breast cancer per local lab test* **Only 1 prior line of systemic treatment (palbociclib and AI) in the locally advanced or metastatic setting is allowed; must have shown progression on palbociclib and AI prior to enrollment* **Fresh tumor tissue specimen prior to enrollment, which must be obtained after evidence of progression on first-line palbociclib and AI* **Measurable disease (RECIST) Version 1.1 is required* **Lesions in a previously irradiated area that have not progressed are not considered measurable.*	Phase 1b/2 Study of the Addition of STAT3 Inhibitor TT1-101 to Reverse Resistance on First Line Palbocilib Plus Aromatase Inhibitor Therapy for Metastatic Hormone-Receptor Positive and HER2-Negative Breast Cancer **Tvardi Therapeutics Inc. TVD-1001-0002B** **NCT05384119** https://clinicaltrials.gov/ct2/show/NCT05384119
**Tumors are PD-L1 negative at screening or PD-L1 positive at screening if they have received anti-PD-(L)1 inhibitor in the (neo)adjuvant setting* **Centrally confirmed TNBC and PD-L1 status on fresh or archival tissue* **Must have completed treatment for Stage I-III breast cancer, if indicated, and ≥ 6 months must have elapsed between completion of treatment with curative intent and first documented local or distant disease recurrence* **De novo metastatic TNBC are eligible* **Measurable disease based on CT or MRI, RECIST 1.1, evaluated locally* **ECOG performance status of 0 or 1* **Adequate organ function* **HIV patients must be on antiretroviral therapy (ART) and have a well-controlled HIV infection/disease*	A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Patients With Previously Untreated, Locally Advanced, Inoperable or Metastatic Triple-Negative Breast Cancer Whose Tumors Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumors do Express PD-L1 **Gilead GS-US-592-6238** **NCT05382299** https://clinicaltrials.gov/ct2/show/NCT05382299
**Treatment Period has 2 groups* **1 - tamoxifen concurrently with TOL2506* **2 - start with an AI (letrozole, anastrozole, or exemestane) 6 weeks after the first administration of TOL2506, upon confirmation that estradiol (E2) levels of < 20 pg/mL have been achieved.* **After Week 12, subjects can switch from receiving an AI to receiving tamoxifen or from tamoxifen to AI at discretion of the Investigator.* **Switch not permitted 28 days prior to a dosing visit.* **At the end of the Treatment Period, subjects eligible for compassionate use of TOL2506 (expanded access) until TOL2506 is commercially available.*	Phase 3, Single Arm, Open-Label Study Evaluating Ovarian Suppression Following Three-Month Leuprolide Acetate Injectable Suspension (TOL2506) in Combination with Endocrine Therapy in Premenopausal Subjects with Hormone-Receptor–Positive (HR+), Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Breast Cancer) **TolMar TOL2506A** **NCT04906395** https://clinicaltrials.gov/ct2/show/NCT04906395

Breast (Continued)	
**Untreated MBC HR+* **1 or more elevated breast markers (CEA, CA15-3, CA27.29)* **need at least 2 markers done* **No brain mets*	Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer **S1703 (NCORP)** **NCT03723928** https://clinicaltrials.gov/ct2/show/NCT03723928
**Bone dominant MBC* **Plan to receive 1st/2nd line ET, chemo or HER2 targeted therapy* **NO greater than 3 lines of tx*	FDG PET to Assess Therapeutic Response in Patients with Bone-Dominant Metastatic Breast Cancer, FEATURE **EA1183 (NCORP)** **NCT04316117** https://clinicaltrials.gov/ct2/show/NCT04316117

Urothelial	
**MIBC (T2-T4AN0M0)* **LN>10MM need bx. (suitable for neo-adj.)* **Staging & TURBT w/in 70days of rando.* **NO prior tx.* **For MIBC* **No radical cystectomy*	Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer **S1806 (NORP)** **NCT03775265** https://clinicaltrials.gov/ct2/show/NCT03775265

Head and Neck	
**Oropharynx cancer (AJCC 8) that is p16-positive by with: ≥ 10 pack-years, stage T1-2N2-N3 or T3-4N0-3 OR < 10 pack-years, stage T4N0-N3 or T1-3N2-3* **No prior systemic therapy, radiation, or surgery for p16 positive OPSCC* **No previous radiation for head and neck, skull base, or brain* **No distant metastases/leptomeningeal disease* **No uncontrolled inter-current illness interfering w/ability to undergo therapy* **No prior/2nd malignancy, Must have measurable disease, defined by protocol*	A Phase III Randomized Study of Maintenance Nivolumab vs Observation in Patients w/Locally Advanced, Intermediate Risk HPV Positive OPSCC **NCORP EA3161** **NCT03811015** https://www.clinicaltrials.gov/ct2/show/NCT03811015

Anal and Colorectal	
Stage II-III colorectal cancer patients scheduled to receive oxaliplatin 510 mg/m² (cumulative dose) over 12 weeks as a component of adjuvant FOLFOX* **Age ≥ 25 years.* **Must be able to speak and read English* **Enrollment suspended due to drug supply 3/31/2023	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III **A221805 (NCORP)** **(Sub-study SI1 closed to enrollment)** **NCT04137107** https://clinicaltrials.gov/ct2/show/NCT04137107

**Patient must have inoperable, recurrent, or metastatic disease* **Measureable disease* **No prior treatment for metastatic disease*	A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients **EA2176 (NCORP)** **NCT04444921** https://clinicaltrials.gov/ct2/show/NCT04444921
**Histologically/cytologically confirmed Stage IV CRC with BRAF V600E mutation* **Prior systemic treatment in metastatic setting (considered metastatic treatment if relapse/ metastasis < 6 mos from end of adj/neoadj treatmnt* **SLI: 0-1 regimens* **Phase 3: None* **Measurable disease (Phase 3)/ Measurable or evaluable disease (Safety Lead-in)* **ECOG PS 0-1* **Adequate organ function*	An Open-label, Multicenter, Randomized Phase 3 Study of First line Encorafenib Plus Cetuximab With or Without Chemotherapy Agents versus Standard of Care Therapy with a Safety Lead-in of Encorafenib and Cetuximab Plus Chemotherapy In Participants with Metastatic BRAF V600E Mutant Colorectal Cancer **Pfizer C4221015** **NCT04607421** https://clinicaltrials.gov/ct2/show/NCT04607421

Chemo Induced Nausea and Vomiting

**Male or female, Naïve or non-naïve to cancer chemotherapy* **With histologically or cytologically confirmed malignant disease* **Karnofskyindex ≥ 50* **Be scheduled to receive MEC (see Appendix 1) to be administered on Study Day 1 (either alone or in combination with other chemotherapy agents of equal or lesser emetogenicity) Be able to read, understand, and follow the study procedures and able to complete subject diary autonomously* **Discretion of physician ifSubjects w/known non-severe hepatic, non-severe renal, or cardiovascular impairment or a known history or predisposition of cardiac conduction interval abnormalities can be enrolled at the discretion of the investigator* **Discretion of physician if no more than mild nausea following any previous chemo*	A Randomized, Double-blind, Double-dummy, Parallel Group Study to Assess the Efficacy and Safety of Palonosetron HCl Buccal Film versusIV Palonosetron 0.25 mg for the Prevention of Chemotherapy-induced Nausea and Vomiting in Cancer Subjects Receiving Moderately Emetogenic Chemotherapy **Xiamen LP-CT-PALO-202101** **NCT05199818** https://clinicaltrials.gov/ct2/show/NCT05199818

DNA Evaluation or Gene Sequencing

***Cohort B - No Cancer - no cancer diagnosis or stable nodule for at least 1 year by chest CT scan. (~70% no nodules and ~30% stable nodules anticipated)* ***Cohort C - Cancer, Non-Lung primary - pathologic diagnosis of non-lung cancer inclusive of TNM Stage, originating from: esophagus (upper), colon or rectum, pancreas, stomach (including lower esophagus), head & neck, bladder, kidney, or liver.*	DNA Evaluation of Fragments for Early Interception - - Lung Cancer Training Study **DELFI-L101** **(Cohort A closed to enrollment)** **NCT04825834** https://clinicaltrials.gov/ct2/show/NCT04825834
**Must have had/will have at least one dose of anti-PD-1/PD-L1 immunono* **Must have had/will have tumor biopsy prior to anti-PD-1/PD-L1 treatment* **Must have had/will have CT or MRI of tumor prior to anti-PD-1/PD-L1 immunotherapy* **Must have enough tissue available for protocol needs* *CANCERS* **Head and neck squamous cell carcinoma (HNSCC)* **Non-small-cell lung cancer (NSCLC) - *Small cell lung cancer (SCLC)* **Urothelial carcinoma (UCC) - *Cervical cancer* **Gastric or gastroesophageal junction adenocarcinoma* **Esophageal squamous cell carcinoma (ESCC)* **Triple-negative breast cancer (TNBC) - *Hepatocellular carcinoma (HCC)* **Renal cell carcinoma (RCC) - *Colorectal cancer (CRC)*	A Multicenter Cancer Biospecimen Collection Study **Cofactor Genomics, Inc. PREDAPT-2** **NCT04510129** https://clinicaltrials.gov/ct2/show/NCT04510129

Smoldering Multiple Myeloma

**ECOG PS 0-2, and adequate lab values, Measurable disease* **Asymptomatic high-risk smoldering multiple myeloma (SMM) within past 12 months* **Bone marrow aspirate &/or biopsy w/in 42 days of randomization and demonstrate 10-59% clonal plasma cells* **No lytic lesions, plasmacytoma, or unexplained hypercalcemia* **No known COPD or moderate-severe asthma* **No prior/concurrent systemic or radiation therapy for myeloma; *No contraindication to DVT prophylaxis/aspirin* **Not more than 1 focal marrow lesion on MRI of pelvis or spine* **No concurrent use of erythropoietin* **No prior glucocorticosteroid therapy for MML (but other glucocorti-costeroid use is permitted per protocol)* **No active, uncontrolled seizure disorder, or uncontrolled intercurrent illness* **No monoclonal gammopathy of undetermined significance* **No Gr 2 or higher peripheral neuropath* **No active, uncontrolled infection* **History of current/previous DVT or PE allowed but must take anti-coagulation* **No baseline NYHA classification III/IV heart failure* **HIV, HBV, HCV patients are eligible*	Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) **NCORP EAA173** **NCT03937635** https://clinicaltrials.gov/ct2/show/NCT03937635

MDS and AML

MDS, AML, Idiopathic cytopenia of unknown significance Within 60 days of diagnosis Enrolling only LR MDS and Relapsed Myelofibrosis	Connect® MDS and AML: The Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry **Celgene Connect AZA-MDS-006 Registry** **NCT01688011** https://clinicaltrials.gov/ct2/show/NCT01688011
Observational study **RRMM patients with at least 1 prior line* **Prospective - Physician independent of study initiates isatuximab per routine practice* **Retrospective - Exposure to isatuximab for a max 3 months*	A Non-interventional, Multinational, Observational Study With Isatuximab in Patients With Relapsed and/or Refractory Multiple Myeloma (RRMM) **Sanofi OBS16577** **NCT04458831** https://clinicaltrials.gov/ct2/show/NCT04458831

Precision Medicine Basket Trials

Screening: Large 1B; IIA or IIB; NSCLC Squamous Stage IB – IIIA; Free testing for EGFR, ALK and PD-L1	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) **A151216 (NCORP)** **NCT02194738** https://clinicaltrials.gov/ct2/show/NCT02194738

Rollover Studies

**Previously enrolled in a Pembrolizumab Study*	A Multicenter, Open label, Phase III Extension Trial to Study the Long-term Safety and Efficacy in Participants w/Advanced Tumors Who Are Currently on Treatment or in F/up in a Pembrolizumab Trial. **Merck MK-3475-587-00** **NCT03486873** https://clinicaltrials.gov/ct2/show/NCT03486873

Non Small Cell Lung Cancer (NSCLC)	
*Advanced stage (stages IIIB-IV) NSCLC and confirmed METex14 skipping alterations who are initiating or already treated with a systemic therapy	Disease Registry on Patients with Advanced Non-small Cell Lung Cancer (NSCLC) Harboring METex14 Skipping Alterations MOMENT (Met nOn sMall cEll caNcer registry) **EMD Serono MS200095-0050 (MOMENT)** **NCT05376891** https://clinicaltrials.gov/ct2/show/NCT05376891
***Experimental: Arm A: LACP** (Lazertinib, Amivantamab, Carboplatin, and Pemetrexed). After 4 cycles, Lazertinib, Pemetrexed, and Amivantamab as maintenance until PD ***Active Comparator: Arm B: CP** (Carboplatin and Pemetrexed) After 4 cycles, Pemetrexed as maintenance until PD ***Experimental: Arm C: ACP** (Amivantamab, Carboplatin and Pemetrexed) After 4 cycles, Amivantamab and Pemetrexed as maintenance until PD	A Phase 3, Open-Label, Randomized Study of Amivantamab and Lazertinib in Combination with Platinum-Based Chemotherapy Compared w/Platinum-Based Chemotherapy in Patients with EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer After Osimertinib Failure **Janssen 61186372NSC3002 (Mariposa 2)** **NCT04988295** https://clinicaltrials.gov/ct2/show/NCT04988295
*Crizotinib *ALK Fusion Protein if ALK detected on Alchemist screening	A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Vs Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein **E4512 [Alchemist ALK] (NCORP)** **NCT02201992** https://clinicaltrials.gov/ct2/show/NCT02201992
*Newly diagnosed stage IIIA/B/C NSCLC unresectable, histo/cyto confirmed OR nodal recurrence after surgery for early stage NSCLC *Eligible w/nodal recurrence after surgery if no prior chemo/radiation for this lung cancer, prior surgery was at least 90 days prior to nodal recurrence, and no prior radiation that would cause overlap of treatment fields *Measurable disease (RECIST 1.1) * No autoimmune disease and neuromuscular paraneoplastic syndromes *No prior bone marrow or solid organ transplant; no past radiation to current treatment site; no prior systemic treatment w/anti-bodies/drugs targeting T-cell costimulation/immune checkpoint inhibitors *Review protocol for cardiac criteria	Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC **NCORP EA5181** **NCT04092283** https://clinicaltrials.gov/ct2/show/NCT04092283

CONTACTS	
For Research Information call:	**Investigators**
Eileen Georgi, MSN RN - 954-542-7748	David Drew, MD
Ayoola Adigun, IMG, MPH - 954-542-8528	Georges Azzi, MD
Brandon Barker, RN, BSN – 954-542-7718	Neil Nagovski, MD
Shalom Koshy, IMB – 954-542-3037	Karim Arnaout, MD
Manuel De Leon, PharmD – 954-542-3036	Michel Velez, MD