Oncology Clinical Trial List November 2024

Breast	
**HER2-positive- based on pre treatment biopsy, IHC score of 3+ and/or positive by in situ hybridization (ISH). Known HR status.* **Clinical stage T1-4, N0-3 disease and residual invasive disease postop are eligible.* **Residual HR-negative, HER2 positive (+) disease in the breast and/or lymph nodes per the surgical path report are eligible; but HR+ HER2+ cancers must have node-positive residual disease per the surgical path report* **Residual disease tissue not required to be HER2-positive, eligibility based on a positive HER2 status at initial cancer diagnosis* **Micrometastases in lymph nodes after preop therapy counts as residual disease, whereas the presence of isolated tumor cells does not* **Synchronous bilateral invasive disease are eligible provided both lesions were confirmed to be HER2-positive, and at least one lesion meets criteria* **Must have received neoadjuvant chemo with one of: THP; TMP; AC-TH(P); TCH(P); FAC-TH(P), or FEC-TH(P)* **Patients are randomized to 1 of 2 arms.* ***Arm I Active Comparator: (trastuzumab emtansine, placebo): Patients receive trastuzumab emtansine (T-DM1) IV over 30-90 minutes on day 1 & placebo orally (PO) twice daily (BID) on days 1-21. Treatment repeats every 21 days for up to 14 cycles in the absence of disease progression or unacceptable toxicity.* ***Arm II Experimental: (trastuzumab emtansine, tucatinib): Patients receive T-DM1 IV over 30-90 minutes on day 1 and tucatinib PO BID on days 1-21. Treatment repeats every 21 days for up to 14 cycles in the absence of disease progression or unacceptable toxicity.* **After completion of study treatment, patients are followed up at 30 days, then every 6 months for 10 years.*	THE COMPASSHER2 TRIALS (COMPREHENSIVE USE OF PATHOLOGIC RESPONSE ASSESSMENT TO OPTIMIZE THERAPY IN HER2-POSITIVE BREAST CANCER): COMPASSHER2 RESIDUAL DISEASE (RD), A DOUBLE-BLINDED, PHASE III RANDOMIZED TRIAL OF T-DM1 AND PLACEBO COMPARED WITH T-DM1 AND TUCATINIB *(Quality of Life Sub-Study Closed)* **NCORP A011801** **NCT04457596** https://clinicaltrials.gov/study/NCT04457596
**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

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: Durvalumab + Tremelimumab + Platinum-based Chemotherapy* **Durvalumab plus tremelimumab q3w for four 21-day cycles in combination with chemotherapy* **Followed by maintenance therapy (durvalumab plus pemetrexed maintenance) every 4 weeks (q4w) until disease progression or unacceptable toxicity or treatment discontinuation.* **During the maintenance therapy phase, participants will receive an additional cycle of durvalumab plus tremelimumab (plus pemetrexed, where applicable) at Week 16.*	A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-Squamous Histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON) **Astra Zeneca D419ML00003 (Triton)** **NCT06008093** https://classic.clinicaltrials.gov/ct2/show/NCT06008093
**Histologically/cytologically confirmed early stage or advanced/metastatic solid tumor, NSCLCl* **Life expectancy at least 3 months* **HIV patients must have well controlled disease on antiretroviral therapy (ART)* **HBsAg positive eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks, & have undetectable HBV before randomization* **HCV eligible if have completed curative antiviral therapy at least 4 weeks before randomization and HCV undetectable at screening* **ECOG 0 to 1 assessed w/in 3 days before study intervention*	A Study of Participant Reported Preference for Subcutaneous Pembrolizumab Coformulated With Hyaluronidase (MK-3475A) Over Intravenous Pembrolizumab (MK-3475) Formulation in Multiple Tumor Types **Merck MK3475A-F11** **NCT06099782** https://clinicaltrials.gov/study/NCT06099782
**Non-squamous NSCLC with documented HER2 mutation in the TKD as per local lab results.* **Has received, in the advanced/metastatic setting, at least one line of systemic therapy* **Patient without active brain metastases or patient with active brain metastases who are not eligible for immediate local therapy, as per investigator evaluation* **ECOG = 2* **Archival or fresh tissue (required and optional)* **Adequate organ function* **Life expectancy at least 12 weeks*	Beamion LUNG-1: An open label, Phase I dose escalation trial, with dose confirmation and expansion, of zongertinib (BI 1810631) as monotherapy in patients with advanced or metastatic solid tumors with HER2 aberrations **Boehringer-Ingelheim 1479-0001** **NCT04886804** https://clinicaltrials.gov/study/NCT04886804

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

DNA Evaluation, Liquid Biopsy, Gene Sequencing	
**Baseline blood draw before initial treatment* **Longitudinal blood draws every month to assess DNA changes* **No samples will be tested until sufficient samples have been collected study wide* **Physicians will not receive results* **However, patients can have blood tested up to 3 times free of charge on commercially available Guardant 360*	SIBYL: obServation of therapy response with lIquid BiopsY evaluation **Guardant 06-MX-001 (SYBIL)** **(Breast cohort closed to enrollment)** **Not listed in NCT**
**Tissue collection for breast* **May also open cohorts for lung, colon, head and neck and other tissue*	A Multi-Center Study for the Collection of Biospecimens for Research; Surplus Surgical Tissues and Surplus/Non-Surplus Biofluids for In-Vitro Research **SERATRIALS- 18004** **(No NCT)**
**Enrolling African American male patients with no cancer diagnosis*	Blinded Reference Set for Multicancer Early Detection Blood Tests **A212102 (NCORP)** **NCT05334069** https://clinicaltrials.gov/study/NCT05334069
**Blood collection for pancreatic and ovarian cancer*	Cancer Tissue, Adjacent Normal Tissue, Urine and Peripheral Whole Blood Translational Oncology: Discovery and Evaluation of Biomarkers/Pharmacogenomics for the Diagnosis and Personalized Management of the Oncology Patient **MT Group MTG-015 Biospecimen** **(No NCT)**
**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**

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 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

Smoldering Multiple Myeloma

**ECOG PS 0-2, and adequate lab values, Measurable disease* **Asymptomatic high-risk 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 (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

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

CONTACTS

For Research Information call:	**Investigators**
Eileen Georgi, MSN RN - 954-542-7748	David Drew, MD
Paulino Four Castro, RN – 954-542-8528	Georges Azzi, MD
Shalom Koshy, IMG – 954-542-3037	Karim Arnaout, MD
Denise Pichardo, RN – 954-542-8565	Michel Velez, MD
Manuel De Leon, PharmD – 954-542-3036	Simon Blanc, MD