Treatment Trials posted March and April 2025

Research Base	Protocol #	Official Study Title	Indication/Disease	Planned Intervention	Abbreviated Eligibility Criteria Please refer to CTSU for the most recent version of the protocol.	Primary Objective	ClinicalTrials.gov NCT #	CTSU Activation Date	Approx. Target Accrual
Canadian Cancer Trials Group (CCTG)	CCTG-BR38	Consolidative Use of Radiotherapy to Block (CURB2) Oligoprogression in Patients With Metastatic Non-Small-Cell Lung Cancer	Lung, Mediastinal, and Pleural Cancer	**Arm 1:** No SBRT and switch to second-line SOC systemic therapy **Arm 2:** SBRT/radiotherapy* to all sites of oligoprogression followed by the same first-line SOC systemic therapy * hypofractionated radiation instead of SBRT is permitted	**PVD: 3/5/2025** **Eligibility Criteria:** * have metastatic disease (stage IV) detected on imaging and histologically confirmed NSCLC without an actionable driver mutation, for whom either ICI alone or combination ICI + chemotherapy is indicated * have Oligoprogression on first-line ICI +/- chemotherapy systemic therapy after at least 3 cycles. (Oligoprogression is defined by RECIST 1.1 or PERCIST, as listed in the protocol). * If applicable, participants with treated stable CNS disease are eligible if they are asymptomatic and do not require ongoing corticosteroids. Patients with new or progressive brain mets are eligible if they are asymptomatic and do not require CNS-specific treatment. * be ≥ 18 years old * have ECOG PS 0-2 * Participants who received prior systemic treatment are eligible if at least 6 months have elapsed between the completion of prior therapy and the start of first-line treatment for metastatic disease. Previous surgery and/or radiation is allowed if clinically significant AEs have resolved. * be sufficiently fluent in English, French, or Spanish to complete the QOLS. (Patients who are lack comprehension or have cognitive issues are ineligible) **Ineligibility Criteria:** * Large-cell neuroendocrine carcinoma (LCNEC), pulmonary carcinoid tumour or mixed small cell and non-small cell lung cancer * Presence of leptomeningeal disease * not actively on ICI alone or ICI + chemotherapy * Live attenuated vaccination administered within 30 days prior to enrollment. (Intranasal vaccines are live vaccines and are not allowed) See protocol for organ, marrow, HIV, HBV, HCV parameters	To evaluate if the addition of SBRT to extra-cranial oligoprogressive metastatic disease can prolong progression-free survival (PFS) and/or overall survival (OS) compared to SOC systemic therapy alone in participants with oligoprogressive NSCLC.	NCT06686771	4/3/2025	320
COG	ARAR2331	Prospective Treatment of Types I, II and III Pleuropulmonary Blastoma (PPB)	Lung, Mediastinal, and Pleural Cancer	**Group I (type I/Ir PPB)** ***Arm 1**: vincristine, dactinomycin, and cyclophosphamide x8 cycles. ***Arm 2:** observation **Group II (Type II/III PPB)** Vincristine, Topotecan, Cyclophosphamide x2 cycles. If CR, PR, or SD after cycle 2, go on to Arm 3. If PD after cycle 2, go on to Arm 4. **Arm 3:** ***Cycles 3-6 (IVADo):** Vincristine, dactinomycin, ifosfamide, dexrazoxane, doxorubicin x4 cycles ***Cycles 7, 9, 11 (VTC250):** vincristine, topotecan, cyclophosphamide x3 odd cycles. ***Cycles 8, 10, 12 (VAC1200):** vincristine, dactinomycin, cyclophosphamide x3 even cycles **Arm 4:** ***Cycles 3-6 (IVADo):** Vincristine, dactinomycin, ifosfamide, dexrazoxane, doxorubicin x4 cycles ***Cycles 7-12 (IVA):** vincristine, dactinomycin and ifosfamide x6 cycles	**PVD: 3/3/2025** **Patient Inclusion:** * Must be ≤ 21 * Newly diagnosed Pleuropulmonary Blastoma (PPB). Patients with known germline DICER1 variant or mosaicism with a large, solid unresectable thoracic mass with Type II or III PPB are eligible if a bx is not feasible. * Adequate organ function (outlined in the protocol) is required for Type II or III PPB. There are no specific organ function requirements for Type I or Ir PPB * Shortening fraction of ≥ 27% by ECHO, or Ejection fraction of ≥ 50% by radionuclide angiogram **Patient Exclusion:** * Administration of prior PPB-directed chemotherapy. Prior tx for another malignancy is allowed. * Known Charcot-Marie-Tooth disease **See protocol for organ, marrow, and HIV parameters**	To estimate 3-year PFS and OS in children with Types II and III PPB. To estimate 3-year PFS and OS in children with Type I PPB treated with surgery or surgery and chemotherapy using standardized guidelines.	NCT06647953	3/17/2025	110

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COG	AREN2231	Risk Adapted Treatment of Unilateral Favorable Histology Wilms Tumors (FHWT)	Kidney Cancer	This study includes a cohort of patients treated with Nephrectomy only and 6 chemotherapy treatment regimens: **1. EE-4A** (vinCRIStine, DACTINomycin) **2. DD-4A** (vinCRIStine, DACTINomycin, DOXOrubicin) **3. VIVA** (vinCRIStine, DACTINomycin, irinotecan) **4. M** (vinCRIStine, DACTINomycin, DOXOrubicin, cyclophosphamide and etoposide) **5. MVI** (vinCRIStine, DACTINomycin, DOXOrubicin, cyclophosphamide, etoposide and irinotecan) **6. UH-3** (vinCRIStine, DOXOrubicin, cyclophosphamide, etoposide, CARBOplatin, and irinotecan). All patients receiving chemotherapy (regardless of stratum assignment) will start with 1 cycle (3 weeks) of VA (vinCRIStine, DACTINomycin) chemotherapy.	**PVD: 2/20/2025** **Patient Inclusion:** * Must be < 30 * Newly diagnosed Stage I-IV Favorable Histology Wilms Tumor confirmed by central review and with a qualifying Initial Stratum Assignment received on APEC14B1-REN * Patients who have an upfront nephrectomy must have at least one lymph node sampled and confirmed as a lymph node by central pathology review to be eligible * KPS ≥ 50 for patients > 16 years of age and the Lansky performance status must be ≥ 50 for patients ≤ 16 years of age * Shortening fraction of ≥ 27% by echocardiogram, or ejection fraction of ≥ 50% **Patient Exclusion:** * diagnosis of Stage V Bilateral Wilms Tumor * Stage I FHWT with a known or suspected Wilms Tumor predisposition syndrome or condition (contralateral nephrogenic rests and/or unilateral multicentric tumors) are excluded from treatment on the mVLR (Nephrectomy Only) arm. (See protocol for description of WT syndromes and conditions). * Patients treated with partial nephrectomy at initial diagnosis are excluded from mVLR (Nephrectomy Only) arm * Patients with lung metastases as the only metastatic site who already had complete resection of all radiologically evident lung nodules, and have at least one nodule * Patients who have had prior tumor-directed chemotherapy or radiotherapy for the current diagnosis except for therapy delivered for an emergent issue, as medically indicated. * Known Charcot-Marie-Tooth syndrome * Patients who will potentially require doxorubicin on this study and have previously received doxorubicin for another diagnosis * See protocol for organ, cardiac, and HIV parameters.	Unable to abbreviate; refer to the protocol or ClinicalTrials.gov NCT06401330	NCT06401330	3/28/2025	1656
SWOG	MM1OA-S03	A Randomized Phase II Trial of ASTX727 and Venetoclax Compared with ASTX727, Venetoclax, and Enasidenib for Newly Diagnosed Older Adults with IDH2 Mutant Acute Myeloid Leukemia: A MyeloMATCH Substudy	Leukemia	**Arm 1:** ASTX727 (PO D1-5) and Venetoclax (PO D1-28) **Arm 2:** ASTX727 (PO D1-5), Venetoclax (PO D1-28), and Enasidenib (PO D1-28)	**PVD 2/28/2025** **Eligibility Criteria:** * Must have been registered to the MYELOMATCH Master Screening and Reassessment Protocol prior to consenting to this study. * Must have newly diagnosed, untreated acute myeloid leukemia (AML), with ≥ 20% blasts in the bone marrow and/or peripheral blood, excluding acute promyelocytic leukemia (APL) with PML-RARA * Must be ≥ 60 years old; or ≥ 18 years old and considered not eligible for cytarabine-based induction therapy. * Must have a Zubrod Performance Status of 0-3 * Must be able to swallow and retain oral medications and have no known gastrointestinal absorption disorders * Must not have received prior therapy for AML or MDS and/or MPN with the exception of hydroxyurea, all-trans retinoic acid (ATRA), colony-stimulating factors, erythropoiesis-stimulating agents, immunosuppressive therapy, intrathecal chemotherapy, a single dose of cytarabine for cytoreduction, and/or leukapheresis. * Must not be currently receiving any cytarabine-containing therapy other than up to 1 g/m2 of cytarabine * Must not have a baseline corrected QT interval ≥480 msec using Fridericia correction (QTcF) * See protocol for organ, cardiac, HIV, HBV, and HCV parameters	a. To evaluate the safety of ASTX727 + venetoclax + enasidenib (Arm 2) before initiating randomization. b. To compare the rate of measurable residual disease (MRD) negative complete remission (CR) based on multiparameter flow cytometry (MFC) after two cycles of treatment in older adults (or unfit adults age 18 or older) with IDH2 mutated Acute Myeloid Leukemia (AML) who receive ASTX727, venetoclax, and enasidenib versus ASTX727 and venetoclax alone.	NCT06672146	4/1/2025	93

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SWOG	S2414	A Randomized Phase III Trial INcorporating Pathologic Complete ReSponse in Participants with Early StaGe Non Small Cell Lung Cancer to Optimize ImmunotHerapy in the AdjuvanT Setting (INSIGHT)	Lung, Mediastinal, and Pleural Cancer	**Arm 1:** Durvalumab q28 days x 12 cycles **Arm 2:** Surveillance	**PVD: 3/11/2025** Eligibility Criteria: * Must have histologically or cytological confirmed diagnosis of clinical Stage II-IIIB (excluding clinical N3 disease) (as defined in Section 4.0) non-small cell lung cancer (NSCLC) * Must have had a complete (R0) resection of NSCLC (with appropriate lymph node sampling as defined by the NCCN Guidelines * Must have a pathologic complete response (pCR) (no viable tumor in the resected specimen or lymph nodes) * Must have a PD-L1 status result * Must not have known EGFR mutations, or ALK gene fusion * Must have received at least two cycles of neoadjuvant platinum-based chemotherapy and anti-PD-1 or anti-PD-L1 therapy * Must not have received any prior systemic therapy (systemic chemotherapy, immunotherapy or investigational drug) within 28 days prior to randomization * Must not have received post-operative radiation therapy (PORT) for NSCLC * Must be ≥ 18 years old at time of study entry. * Must have body weight > 30 kg. * Must have Zubrod Performance Status of 0-2 * Must not have received a live or live attenuated vaccine within 28 days prior randomization * See protocol for lab, HIV, Hep B, and Hep C parameters	To compare disease free survival (DFS) in stage II-IIIB non-small cell lung cancer participants who achieved a pathologic complete response (pCR) following standard of care neoadjuvant chemo-immunotherapy and are randomized to adjuvant durvalumab (MEDI4736) versus surveillance.	NCT06498635	3/14/2025	306