Treatment Trials Activated October 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
ECOG	EA8231	A Phase III Randomized Trial of Pembrolizumab in Combination with Sacituzumab Govitecan vs Standard of Care in Anti-PD(L)1-Resistant Advanced Urothelial Cancer	Urothelial/ Bladder Cancer	**Arm A: TPC (Therapy per Physician Choice)** - SOC 1 cycle = 21 days (+/- 3 days) 1. Platinum doublet a) Carboplatin AUC 4-5 Day 1 + Gemcitabine 1000mg/m2 Days 1 and 8 every 21 days. Continue treatment until a maximum of 6 cycles. b) Cisplatin 70mg/m2 Day 1+ Gemcitabine 1000mg/m2 Days 1 and 8 every 21 days. Continue treatment until a maximum of 6 cycles. 2. Docetaxel 75mg/m2 Day 1 every 21 days. Continue treatment until disease progression6 or unacceptable toxicity. 3. Paclitaxel 80mg/m2 Days 1 and 8, every 21 days. Continue treatment until disease progression6 or unacceptable toxicity. **Arm B: Sacituzumab (SG) + Pembrolizumab** 1 cycle = 21 days (+/- 3 days) Sacituzumab govitecan (SG) 10 mg/kg on Days 1 and 8 + Pembrolizumab 200mg on Day 1 every 21 days.5 Continue treatment until disease progression6 or unacceptable toxicity	**PVD 7/29/2025** **Must have:** 1. Locally advanced (unresectable) or metastatic urothelial carcinoma 2. Bellmunt score 0-2 3. Prior exposure to anti-PD(L)1therapy required1,2 4. Patients must have had line of systemic therapy given in the advanced/metastatic disease setting. For tumors with FGFR3(+) susceptible alteration (for FGFR inhibitor), patients must have received a prior FGFR inhibitor unless contraindicated per physician discretion. 5. Patients must have not had progression to prior anti-PD(L)1 within 12 weeks from therapy start per physician discretion. 6. Prior exposure to enfortumab vedotin unless contraindicated2 **Stratification Factors:** 1. Bellmunt Score (0-1 vs 2) 2. Prior lines of therapy (≤ 2 lines vs > 2 lines) 3. Prior exposure to platinumbased chemotherapy3 (yes prior exposure vs. no, prior exposure and platinumeligible per physician's discretion vs. no, prior exposure and not platinumindigible per physician's discretion) 4. Duration of prior exposure to anti-PD(L)1 therapy **Must not have:** 1. Patient must have had no prior exposure to sacituzumab govitecan or other TROP-2 directed therapies or antibody-drug conjugate that contains topo-isomerase I inhibitor, e.g. trastuzumab	To compare overall survival (OS) between the Therapy of Physician Choice (TPC) arm and the sacituzumab govitecan + pembrolizumab arm.	NCT06524544	10/23/25	320
ALLIANCE	A092204	A Phase II Study of Cabozantinib in Combination with Cemiplimab (REGN2810) (Cabo-Cemiplimab (REGN-2810)) Versus Cabozantinib Alone in Adolescents and Adults with Advanced Adrenocortical Cancer	Endocrine Cancer	**Arm 1 (control):** CCRT Cisplatin (40 mg/m2) QW for 5 weeks + EBRT followed by BT + pembrolizumab (200mg) q3W for 5 cycles + Pembrolizumab (200mg) for 5 cycles Q3W Pembrolizumab maintenance (400mg) Q6W for 15 cycles doses #6-20 **Arm 2:** Induction QW carboplatin AUC2 and paclitaxel (80mg/m2) for 6 weeks+ Pembrolizumab (200mg) Q3W for 2 cycles CCRT Cisplatin (40 mg/m2) QW for 5 weeks + EBRT followed by BT + pembrolizumab (200mg) q 3W for 5 cycles + Pembrolizumab (200mg) Q3W for 5 cycles Pembrolizumab maintenance (400mg) Q6W for 14 cycles doses# 8-21 Concurrent chemoradiation therapy (CCRT) External beam radiation therapy (EBRT) Brachytherapy (BT)	**PVD 7/14/2025** **Must have:** Histologically or cytologically documented adrenocortical carcinoma. -Locally advanced unresectable or recurrent/metastatic disease. -Measurable disease as defined in Section 11.0. -No more than 3 prior lines of systemic therapy allowed in the unresectable/recurrent/metastatic setting. -Treatment naïve patients are allowed. -Completed all prior anti-cancer treatment, (except prior mitotane) including radiation, ≥ 14 days prior to registration. -Patients who received mitotane therapy ≤ 6 months prior to registration must have discontinued mitotane at least 28 days prior to registration AND have a mitotane level < 2 mg/L prior to registration (See Section 3.2.3). -Age 12 years and above, and BSA ≥1.2m2 - -ECOG Performance Status 0 – 2 (age ≥ 18 and above); for patients ≥ 12 - <16 years of age assessed by Lansky scale (score ≥50), ≥ 16 - < 18 years, PS assessed by the Karnofsky scale (score ≥ 50). **Must not have:** *No known history of congenital long QT syndrome. *No known history of myocarditis *No MI or unstable angina within 6 months of registration. *No clinically significant gastrointestinal abnormalities that may increase the risk for	To determine whether the combination of cabozantinib plus cemiplimab (REGN2810) (CaboCemiplimab (REGN2810)) improves progression-free survival (PFS) per RECIST v1.1 relative to Cabozantinib alone in patients with locally advanced unresectable or recurrent/metastatic advanced adrenocortical cancer.	NCT06900595	10/22/25	48
COG	AEWS2431	Randomized Phase 2/3 Trial of Vincristine-Irinotecan-Regorafenib in Combination with Vincristine-Doxorubicin-Cyclophosphamide (VDC) and Ifosfamide-Etoposide (IE) in Patients with Newly Diagnosed Metastatic Ewing Sarcoma	Bone Cancer	Overview of Treatment Plan All patients will initiate treatment with interval compressed Induction Therapy with vinCRIStine-DOXOrubicin-cycloPHOSphamide/ifosfamide-etoposide (VDC/IE) for 6 cycles followed by investigator choice of local control and then Consolidation I with an additional 4 cycles of interval compressed VDC/IE. After a total of 10 cycles of therapy, patients with central fusion testing consistent with a diagnosis of Ewing sarcoma will be randomized to either Regimen A or Regimen B. Regimen A will consist of 7 cycles of VC/IE lasting 14 weeks. Regimen B will consist of 6 cycles of vinCRIStine-irinotecanregorafenib (VIrR) lasting 18 weeks. Patients with central fusion testing consistent with a diagnosis of other eligible metastatic round cell sarcoma will be non-randomly assigned to Regimen A. Patients without an eligible translation or inability to complete testing due to lack of adequate tissue will be removed from study. After systemic therapy is completed on both regimens, patients will receive metastatic site radiation and then be considered off protocol therapy.	**PVD 4/21/2025** **Important note:** The eligibility criteria listed below are interpreted literally and cannot be waived. All clinical and laboratory data required for determining eligibility of a patient enrolled on this trial must be available in the patient's medical/research record which will serve as the source document for verification at the time of audit. - Enrollment on APEC14B1 and Consent to Molecular Characterization All patients must be enrolled on APEC14B1 and consented to the Molecular Characterization Initiative (Part A) prior to enrollment and treatment on AEWS2431. - Patients must be ≥ 12 months to ≤ 50 years of age at time of enrollment. - Newly diagnosed Ewing sarcoma and other round cell sarcomas as follows. For the purposes of eligibility, the following pathology diagnoses are eligible and molecular confirmation is not required to enroll: • Histologically confirmed Ewing sarcoma • Suspected Ewing sarcoma with molecular confirmation pending • Suspected high grade round cell sarcomas/sarcomas with eligible molecular alterations as per Table 2.1 (see Section 2.3), pending molecular confirmation • Round cell sarcoma consistent with Ewing sarcoma • Round cell sarcoma not otherwise specified • Round cell sarcoma • Round cell sarcomas with EWSR1-non-ETS fusion • CIC-rearranged sarcoma	To determine if the event-free survival (EFS) in patients with newly diagnosed metastatic Ewing sarcoma is improved when treated with Vincristine-IrinotecanRegorafenib (VIrR) after initial treatment with Vincristine-DoxorubicinCyclophosphamide (VDC) and Ifosfamide-Etoposide (IE) compared to patients treated with 17 cycles of interval compressed VDC and IE chemotherapy.	NCT06820957	10/20/25	159
SWOG	NRG	Phase III Randomized Trial of IO-Based Systemic Treatment +/- Liver SBRT in Hepatocellular Cancer with Macrovascular Invasion (HELIO-RT)	Gastrointestinal Cancer	Patients will recieve MD's choice of Neoadjuvant Therapy (NAT). After Central Radiation plan approval, bladder radiotherapy will commence, followed by x12 months of Pembro (MK-3475).	**PVD 9/10/2025** **Must have:** Patients must have adequate health that permits completion of the study requirements and required follow-up. • For patients with known HIV, HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. • Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial. **Must not have:** * No prior systemic therapy or transarterial radioembolization (TARE) for HCC. • No history of liver transplantation. * No prior radiotherapy to the region of the study cancer that would result in significant overlap of radiation therapy fields that would lead to excessive cumulative toxicity at the discretion of the investigator. * No medical contraindication to the standard of care immunotherapy. • For patients to be treated with atezolizumab/bevacizumab: - No history of a GI bleed or other clinically significant bleeding event within 6 months prior to study registration.	To determine if liver SBRT in combination with IO-based systemic therapy improves survival compared to IO-based systemic therapy alone, in patients with hepatocellular cancer with macrovascular invasion.	NCT07166406	10/7/25	478