Treatment Trials Activated September 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
Alliance	A032302	Docetaxel Addition in Metastatic Castrate-Sensitive Prostate Cancer (ASPIRE)	Adenocarcinoma of the prostate	Treatment is to continue until disease progression or withdrawal. **Arm 1**: ADT + Apalutamide **Arm 2:** ADT + Apalutamide + Docetaxel x 6 doses	**PVD 7/9/2025** **Must have:** * histologically or cytologically confirmed adenocarcinoma of the prostate without small cell histology * metastatic disease based on conventional CT/MRI and/or bone scan. * next generation sequencing (NGS) results from any tissue based CLIA test must be available. Patients with failed NGS testing are not eligible. * be ≥ 18 years * an ECOG Performance Status ≤ 2 **Must not have:** * metachronous low-volume disease (recurrent metastatic disease after definitive treatment of prostate primary) and with ≤ 4 bone metastasis and no visceral metastasis on conventional imaging * received any prior chemotherapy for prostate cancer. * Patients with treated leptomeningeal metastases are eligible if follow-up brain imaging 30 days after CNS-directed therapy shows no evidence of progression. * ADT (LHRH agonist/antagonist or orchiectomy) with or without first generation anti-androgen, or second-generation ARSI within 120 days of registration is permitted. No washout period will be needed for the first generation- androgen or ARSI prior to registration. See protocol for organ, marrow, HIV, Hep B, Hep C, cardiac, and CYP3A4 parameters	To determine if the addition of docetaxel to androgen deprivation therapy and apalutamide improves overall survival for men with metastatic castrate sensitive prostate cancer.	NCT06931340	9/26/2025	1200
NRG	NRG-GY037	A Phase III Study of Induction Pembrolizumab and Chemotherapy Followed by Chemoradiation and Pembrolizumab vs Chemoradiation and Pembrolizumab Both Followed by Pembrolizumab for High Risk Locally Advanced Cervical Cancer	Pathologically confirmed newly diagnosed cervical 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 8/13/2025** **Must have:** * pathologically confirmed newly diagnosed cervical cancer. Eligible pathologic types: squamous cell carcinoma, adenocarcinoma, adenosquamous cell carcinoma * locally advanced cervical cancer (LACC) with T3 or T4 disease with or without lymph node involvement. No paraaortic lymph node (PALN) metastases above the T12/L1 interspace. (See the protocol for FIGO, TMN, and Nodal staging) * be age ≥ 18 * ECOG ≤ 2 **Must not have:** * prior definitive surgical, radiation, or systemic therapy for cervical cancer. * prior immunotherapy. * prior pelvic radiation therapy for any disease. * prior hysterectomy defined as removal of the entire uterus. Prior partial/subtotal hysterectomy for reasons other than cervical cancer are eligible to participate in the study. No plan to perform a hysterectomy as part of initial cervical cancer therapy. * diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior registration. See the protocol for organ, marrow, cardiac, and prohibited vaccination parameters.	To determine whether induction IO and chemotherapy prior to CCRT+IO improves progression-free survival (PFS) compared to CCRT+IO alone.	NCT07061977	9/29/2025	336

SWOG	S2409	PRISM: PRecIsion in SCLC Via a Multicohort Study: Randomized Phase II Studies Evaluating Maintenance Durvalumab with or Without Biomarker-Directed Therapy for Extensive Stage Small Cell Lung Cancer (ES-SCLC)	Histologically or pathologically confirmed diagnosis of extensive stage small cell lung cancer (ES-SCLC)	**INDUCTION:** Patients may receive a platinum Prior to Step 2, participants should receive a total of 4-6 cycles of induction therapy including: • a total of 4 doses of durvalumab (MEDI4736) • a total of 4-6 cycles of platinum plus etoposideInduction **CONSOLIDATION:** Patients may undergo thoracic radiation as clinically indicated. **MAINTENANCE:** Based on Step 1 subtype and SLFN11 status, patient will be assigned to 1 or 3 maintenance cohorts: * Arm A1, B1, and C1: Durvalumab(MEDI4736) * Arm A2: Durvalumab (MEDI4736) + saruparib * Arm B2: Durvalumab (MEDI4736) + ceralasertib * Arm C2: Durvalumab (MEDI4736) + monalizumab	**PVD 4/11/2025** **For Step 1:** * Must have histologically or pathologically confirmed diagnosis of extensive stage small cell lung cancer (ES-SCLC) * Must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the safety or efficacy assessment of the investigational regimen. * Must not have a history of limited stage small cell lung cancer * Must have meet one of the following prior/concurent treatment criteria: a. Treatment naïve and planning to receive frontline induction treatment with platinum plus etoposide in combination with durvalumab, OR, b. Have initiated frontline induction therapy and completed at least 1 (≥ 1) cycle and at most 3 (≤ 3) cycles of platinum and etoposide. At most 2 (≤ 2) of these cycles could have been given without durvalumab. * Must not have received any anti PD-1 or anti PD-L1 (including durvalumab [MEDI4736]) treatment for SCLC prior to starting or as part of frontline induction treatment for ES-SCLC. * Must have not received atezolizumab, pembrolizumab, or nivolumab as part of frontline induction treatment. * Must be ≥ 18 * Must have Zubrod Performance Status of 0-2 * Must not have had an allogenic organ transplantation * Must have adequate tumor tissue available from SCLC available, submitted, and any leftover tissue retained for future correlative studies.	To test participants' tissue specimens to determine their eligibility to 1 of the 3 treatment cohorts created based on their small cell lung cancer (SCLC) subtype and SLFN11 status. This will be assessed primarily by the Screen Success Rate, as defined in Section 10.5.	NCT06769126	9/8/2025	900
SWOG	S2427	Single Arm Phase II Study of Bladder Preservation with Immunoradiotherapy After a Clinically Meaningful Response to Neoadjuvant Therapy in Patients with Muscle Invasive Bladder Cancer (BRIGHT)	Histologic evidence of cT2-T4aN0M0 muscle invasive urothelial carcinoma of the bladder	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 8/1/2025** **Must have:** * histologic evidence of cT2-T4aN0M0 muscle invasive urothelial carcinoma of the bladder * undergone TURBT with biopsy of areas of prior disease and systematic biopsies and radiologic staging showing clinically T0-T1 disease * received at least 3 and no more than 6 cycles of NCCN guideline concordant NAT for MIBC * be ≥ 18 years * have Zubrod Performance Status of 0-2 **Must not have:** * evidence of ≥T2, N1-3 or metastatic disease after NAT * presence of small cell, neuroendocrine carcinoma, plasmacytoid variants on any pathology * had urothelial carcinoma or histological variant at any site outside of the urinary bladder within 24 months prior to registration except Ta/T1/Carcinoma in situ (CIS) of the upper urinary tract, including renal pelvis or ureter if the participant underwent complete nephroureterectomy * prior pelvic radiotherapy * anti-PD-1, anti PD-L1, anti PD-L2 or anti-CTLA4 antibody, any other antibody or drug targeting T-cell co-stimulation, enfortumab vedotin, or any other drug targeting Nectin-4 See the protocol for organ, marrow, prohibited vaccinations, cardiac, HIV, HBV, and HCV parameters	To evaluate whether 3-year bladder intact event-free survival (BI-EFS) is at least 70% in participants with clinically T0-clinically T1 without multifocal CIS following neoadjuvant therapy (NAT) for muscle-invasive bladder cancer (MIBC) who receive radiotherapy (RT) + pembrolizumab (MK-3475).	NCT07061964	9/4/2025	111