

Pediatric Clinical Trials Office Research (PCTO)
Solid Tumor Clinical Trials Portfolio

Sponsor ID	Protocol Title	Basic Eligibility	Status
Newly diagnosed			
MCC20339 Sunshine	Evolutionary Inspired Therapy for Newly Diagnosed, Metastatic, Fusion Positive Rhabdomyosarcoma	PAX/FOXO1 Fusion +, 4 arms, Ability to take oral ctx on arm B	Active, enrolling
MCC20320	Biology study: blood based biomarkers for minimal residual disease detection in pediatric sarcomas	<40 yrs old; newly suspected or confirmed dx.	Active, enrolling
AOST2031	A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients With Osteosarcoma	Age up to 50, new dx with lung mets or at recurrence; NO other mets or prior pulmonary resection.	Active, Enrolling
NMTRC012 BCC	Peds Plan: A Study Using Molecular Guided Therapy with Induction Chemotherapy followed by a Randomized Controlled Trial of standard immunotherapy with or without DFMO followed by DFMO maintenance for Subjects with Newly Diagnosed High-Risk NBL	Part A: Closed Part B: Enrollment w/in 120 days post-transplant	Active, Part A closed. Part B open
BCC018	A Phase II Study of Naxitamab Added to Induction Therapy for Subjects With Newly Diagnosed High-Risk Neuroblastoma	Age 1-21	Active, Enrolling
ANBL1531	A Phase 3 Study of 131I-Metaiodobenzylguanidine (131I-MIBG) or Crizotinib Added to Intensive Therapy for Children with Newly Diagnosed High-Risk NBL	High Risk NBL; must be enrolled on ANBL00B1; Age ≥1 to ≤ 30	Active, Enrolling
ANBL1232	Utilizing Response- and Biology-Based Risk Factors to Guide Therapy in Patients with Non-High-Risk Neuroblastoma	Pts < 12 months with new dx INRG Stage L1 ; Pts < 18 months with new dx INRG Stage L2 or Stage Ms dx. MYCN non-amplified only	Active, Enrolling strata 1 & 3 only

AHEP1531	Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT)	Age <30; HBL or HCC; rapid central imaging & pathology thru PEC	Active, Enrolling: Arm D closed
ARST1431	A Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus in Patients with Intermediate Risk (IR) Rhabdomyosarcoma (RMS)	≤ 40 years of age, Patients with newly dx RMS of any subtype, except adult-type pleomorphic	Temporarily closed 1-6-22
ARST2031	A Study to Compare Early Use of Vinorelbine and Maintenance Therapy for Patients With High Risk Rhabdomyosarcoma	Age ≤ 50	Active, Enrolling
ARST2032	A Phase 3 Study of Patients with Newly Diagnosed Very Low-risk and Low-risk Fusion Negative RMS	Must consent to APEC14B1 MCI first. <21yr, newly dx ERMS, spindle cell/sclerosing RMS, or FOXO1 fusion neg ARMS	Active, Enrolling
AGCT1531	A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with GCTs	Age criteria dependent on risk group	Active, Enrolling
AGCT1532	A Randomized Phase 3 Trial of Accelerated versus Standard BEP Chemotherapy for Patients with Intermediate and Poor-risk Metastatic Germ Cell Tumors	Age ≥ 11 to ≤ 45; primary arising in testis, ovary, retro-peritoneum, or mediastinum; met dz or non-testicular primary	Active, Enrolling
AREN1721	A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups	Age ≥12 months, BSA ≥0.53, life expectancy ≥8wks, measureable dz, able to swallow tablets	Active, Enrolling
AREN1921	Treatment of Newly Diagnosed Diffuse Anaplastic Wilms Tumors (DAWT) and Relapsed Favorable Histology Wilms Tumors (FHWT)	Age ≤ 30; enroll w/in 2 wks of surgery/bx; New stage 2-4 DAWT OR 1st relapse fav histology Wilms	Active, Enrolling

ARST1921	A Safety, Pharmacokinetic and Efficacy Study of a γ -Secretase Inhibitor, Nirogacestat , in Children and Adolescents with Progressive, Surgically Unresectable Desmoid Tumors	1 to < 18 years of age, a BSA of > 0.3, progressive desmoid tumor	Temp. Closed
ARET2121	Intravitreal Melphalan for Intraocular Retinoblastoma	Age up to 18, Group D eye with vitreous seeding, NO prior anti-cancer therapy	Active, Enrolling
Complete Remission/Best response			
Beat Childhood Cancer NMTRC014	Neuroblastoma Maintenance Therapy Trial Using Difluoromethylornithine (DFMO)	HRNBL in complete remission after upfront tx Age \leq 30.99; within 60 days of EOT; BSA \geq 0.25	Stratum 1 & 2 open; 3 & 4 closed
Relapsed/Refractory			
APEC1621SC Pediatric Match	NCI-COG Pediatric Match (Molecular Analysis For Therapy Choice) Screening Protocol. Only certain ones open at this time.	Age 1- \leq 21; r/r solid tumors, including CNS tumors. Can use FO results to target	Active, Enrolling
ANBL1821	A Phase 2 Randomized Study of Irinotecan/Temozolomide/Dinutuximab with or without Eflornithine (DFMO) in Children with Relapsed, Refractory or Progressive Neuroblastoma	R/R NBL, \geq 1 year of age; no prior IRN/TMZ; no steroids	Active, Enrolling
PEPN2011	A Phase 1/2 Study of Tegavivint (NSC#826393) in Children, Adolescents, and Young Adults With Recurrent or Refractory Solid Tumors, Including Lymphomas and Desmoid Tumors	Age 1-21 (up to 30 for part B); not CNS mets or abnl bone issues	Active
PEPN2111	A Phase 1/2 Trial of CBL0137 in Patients With Relapsed or Refractory Solid Tumors, Including CNS Tumors and Lymphoma	Part A: r/r solid tumor age 1 to \leq 21 Part B2: r/r OST age 1 to \leq 30	Enrollment HOLD
PEPN2112	A Phase 1/ 2 Study of BAY 1895344 (elimusertib , IND#152153, NSC#810486) in Pediatric Patients with Relapsed or Refractory Solid Tumors	Age 1-30 with specific fusions or DNA damage repair gene inactivation's	Enrollment HOLD

PEPN1924	A Phase 2 Study Of Trastuzumab Deruxtecan In Adolescents, Or Young Adults With Recurrent Her2+ Osteosarcoma	Age 12- ≤ 39; mandatory tissue submission for HER2 staining; must have measureable dz	Active, HOLD
ADVL1921	Phase 1 Study to Evaluate the Safety and Pharmacokinetics of Palbociclib (Ibrance®) in Combination with Chemotherapy in Pediatric Patients with Recurrent or Refractory Solid Tumors	Age 2 to < 21; Phase 1 slots for NBL Phase 2 cohort for EWS	Active, Slots available
MCC18613 Sunshine	Phase II Study of nab-Paclitaxel in Combination with Gemcitabine for Treatment of Recurrent/Refractory Sarcoma in Teenagers and Young Adults	Age ≥3 to ≤ 30 years; RMS slots only; must have measureable dz; lansky ≥ 60	Active, 5 slots
MCC19487 Sunshine	A Phase Ib/II Study to Evaluate the Safety, Feasibility and Efficacy of Nivolumab or Nivolumab in Combination With Azacitidine in Patients With Recurrent, Resectable Osteosarcoma	Age up to 39 with isolated pulmonary recurrence	Active; 3 slots
AOST2031	A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients With Osteosarcoma	Age up to 50, new dx with lung mets or at recurrence, rapid central imaging review; NO other mets or prior pulmonary resection.	Active, Enrolling
BCC015	Phase II Trial of Eflornithine (DFMO) and Etoposide for Relapsed/Refractory Neuroblastoma	Age < 31; completed at least 4 cycles of upfront therapy; BSA ≥ 0.25	Active, Enrolling
PEPN2121	Tiragolumab and Atezolizumab for the Treatment of Relapsed or Refractory SMARCB1 or SMARCA4 Deficient Tumors	Age ≥1, r/r OR newly dx'd RMC, extra-CNS rhabdoid, epithelioid sarcoma or SMARC deficient tumors; must have measureable dz	Active, SLOTS available