

Pediatric Clinical Trials Office Research (PCTO)

Sponsor ID	Protocol Title	Basic Eligibility	Status
Newly Diagnosed Leukemia or Lymphoblastic Lymphoma			
AALL1731	A Phase 3 Trial Investigating Blinatumomab (IND# 117467, NSC# 765986) in Combination with Chemotherapy in Patients with Newly Diagnosed Standard Risk or Down syndrome B-Lymphoblastic Leukemia (B-ALL) and the Treatment of Patients with Localized B-Lymphoblastic Lymphoma (B-LLy)	B-ALL w/o DS age 1-10 and initial WBC <50k; B-LLy or DS B-ALL age 1 to ≤ 31 regardless of WBC count	Active, Enrollment HOLD
AALL1732	A Phase 3 Randomized Trial of Inotuzumab Ozogamicin (IND#:133494, NSC#: 772518) for Newly Diagnosed High-Risk B-ALL; Risk-Adapted Post-Induction Therapy for High-Risk B-ALL, Mixed Phenotype Acute Leukemia, and Disseminated B-LLy	Age 1-24; DS and AUL excluded	Active, High risk randomization closed
AALL1631	Phase 3 Trial in Ph+ ALL Testing Imatinib in Combination with Two Different Cytotoxic Chemotherapy Backbones	Age 2-21; BCR-ABL1 rapid review	Active, Enrolling
AALL1721	A Phase II Trial of Tisagenlecleucel in First-line High-risk (HR) Pediatric and Young Adult Patients With B-cell Acute Lymphoblastic Leukemia (B-ALL) Who Are MRD+ at the EOC	Age 1-25; CD19+; Excludes: Ph+, hypodiloid, prior TKI, Burkitt's, genetic syndromes,	Active, HOLD
NYMC575	Induction Chemo-Immunotherapy Followed by Reduced Toxicity Conditioning and Allogeneic Stem Cell Transplant in Advanced Stage Mature Non-anaplastic T-cell or NK Lymphoma/Leukemia	Age 1-31; Excludes: ALCL, active CNS dz, DS	Active, Enrolling
Newly Diagnosed Myeloid Neoplasms			
AAML1831	A phase 3 randomized trial for patients with de novo AML comparing standard therapy including gemtuzumab ozogamicin GO to CPX-351 with GO, and the addition of the FLT3 inhibitor gilteritinib for patients with FLT3 mutations	Age <22; Excluded: Fanconi, DS, Ph+, JMML, MPAL, Schwanman diamond, APL, tx related neoplasm	Active, Strata C & D closed
Relapsed/Refractory Leukemias			
AALL1621	A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND# 133494) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL)	Age 1-21; Blast ≥ 5% Excluded: hx of SOS, isolated CNS, EM or testicular relapse; receiving anti-GVHD meds	Active, Enrolling

AALL1821	A Phase 2 Study of Blinatumomab in Combination with Nivolumab , a Checkpoint Inhibitor of PD-1, in B-ALL Patients Aged ≥ 1 to < 31 Years Old with First Relapse	Age 1 to < 31 ; Excluded: B-LLy, Burkitt L/L, Ph+, MPAL, Charcot-Marie-Tooth, genetic syndromes	Active, Enrollment HOLD
APAL2020SC	Pediatric Acute Leukemia (PedAL) Screening Trial – Developing New Therapies for Relapsed Leukemias	Age up to 22;	Active, Enrolling
Novartis CTL019	Managed Access Program (MAP) to provide access to CTL019, for recurrent or refractory ALL or large B-cell lymphoma patients with out of specification leukapheresis product and/or manufactured tisagenlecleucel out of specification for commercial release	Up to age 25, out of spec and repeat leukapheresis not feasible	Active, Enrolling
Relapsed/Refractory AML			
PEP-CTN ADVL18P1	An Open-Label Feasibility Study to Assess the Safety and Pharmacokinetics of Enasidenib in Pediatric Patients With Relapsed/Refractory Acute Myeloid Leukemia (R/R-AML) With an Isocitrate Dehydrogenase-2 (IDH2) Mutation	Age 2-18; $> 5\%$ blasts at $\geq 2^{\text{nd}}$ relapse or refractory after ≥ 2 inductions; must swallow pills Excluded: CNS dz, DS	Active, Temp closed 8/31/22
PEPN2113	Phase 1 PK study of uproleselan in combination with fludarabine and cytarabine for patients with acute myeloid leukemia, myelodysplastic syndrome or mixed phenotype acute leukemia that expresses E-selectin ligand on the cell membrane and is in second or greater relapse or that is refractory to relapse therapy	Age < 21 , Enrolled thru APAL2020SC; $\geq 1\%$ blasts by central lab.	Active; Temp Closed to Accrual
Other Leukemia Trials			
AAML18P1	Stopping Tyrosine Kinase Inhibitors (TKI) to Assess Treatment-Free Remission (TFR) in Pediatric Chronic Myeloid Leukemia - Chronic Phase (CML-CP)	CML-CP dx'd before age 18; in remission; TKI for minimum 3 years	Active, Enrolling
AAML1921	A Phase I/II Study of Bosutinib in Pediatric Patients With Newly Diagnosed Chronic Phase or Resistant/Intolerant Ph + Chronic Myeloid Leukemia	Age 1-18, Ph+, Resistance or intolerance to TKI, must swallow tabs	Active, Enrolling
Newly diagnosed Lymphoma			

ANHL1931	A Randomized Phase 3 trial of Nivolumab in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma	Age \geq 2; CNS involvement excluded	Active, Enrolling
Relapsed/Refractory Lymphoma			
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	Part A: r/r non Hodgkin lymphoma age 1-12	Active, Enrolling
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 lymphoma age 1-21	Enrollment Hold
PEPN2112	A Phase 1/ 2 Study of BAY 1895344 (elimusertib,) in Pediatric Patients with Relapsed or Refractory Solid Tumors	Age 1-21 with specific fusions or DNA damage repair gene inactivations	Active, Enrolling
ECOG-ACRIN E4412	A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory HL	Age \geq 12 to <18 years; path confirmed relapse or refractory; measurable dz; PFTs; no prior SCT	Active Enrolling
Histiocytoses			
LCH-IV	International Collaborative Treatment Protocol for Children and Adolescents With Langerhans Cell Histiocytosis	Age <18	Active, Stratum 1 Group 2 (SS) closed