

Pediatric CIRB Meeting Agenda

October 8, 2025

I. Amendment Review

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 (Version Date 08/13/25)

II. Amendment Review

ACNS1833, A Phase 3 Randomized Non-Inferiority Study of Carboplatin and Vincristine versus Selumetinib (NSC# 748727, IND# 77782) in Newly Diagnosed or Previously Untreated Low-Grade Glioma (LGG) not associated with BRAFV600E Mutations or Systemic Neurofibromatosis Type 1 (NF1) (Version Date 08/28/25)

III. Amendment Review

ALTE21C1, Assessment of Clonal Hematopoiesis and its Relationship to Cardiovascular Disease in Hodgkin Lymphoma Survivors (Version Date 09/08/25)

IV. Continuing Review

AALL1821, A Phase 2 Study of Blinatumomab (NSC# 765986, IND #147294) in Combination with Nivolumab (NSC# 748726, IND# 147294), a Checkpoint Inhibitor of PD-1, in B-ALL Patients Aged ≥ 1 to <31 Years Old with First Relapse (Version Date 07/18/25)

V. Continuing Review

ACCL2031, A Phase 3 Randomized, Placebo-Controlled Trial Evaluating Memantine (IND #149832) for Neurocognitive Protection in Children Undergoing Cranial Radiotherapy as Part of Treatment for Primary Central Nervous System Tumors (Version Date 04/07/25)

VI. Continuing Review

ACNS1931, A Phase 3 Study of Selumetinib (NSC# 748727, IND# 77782) or Selumetinib in Combination with Vinblastine for non-NF1, non-TSC Patients with Recurrent or Progressive Low-Grade Gliomas (LGGs) Lacking BRAFV600E or IDH1 Mutations (Version Date 05/15/25)

VII. Continuing Review

ARAR2331, Prospective Treatment of Types I, II and III Pleuropulmonary Blastoma (PPB) (Version Date 03/03/25)

VIII. Continuing Review

PBTC-060, A Pilot Study of Safety, Tolerability, and Immunological Effects of SurVaxM in Pediatric Patients with Progressive or Relapsed Medulloblastoma, High Grade Glioma, Ependymoma and Newly Diagnosed Diffuse Intrinsic Pontine Glioma (Version Date 11/13/24)

IX. Continuing Review

PEPN2121, A Phase 1/2 Study of Tiragolumab (NSC# 827799, IND# 161266) and Atezolizumab (NSC# 783608, IND# 161266) in Patients with Relapsed or Refractory SMARCB1 or SMARCA4 Deficient Tumors (Version Date 04/09/25)

X. Continuing Review

PEPN22P1, A Pharmacokinetic Study of VinCRISTine in Infants Dosed According to BSA-Banded Infant Dosing Tables and Older Children Dosed by Traditional BSA Methods (Version Date 07/24/24)

XI. Continuing Review

PEPN2312, A Phase 1 Study of GRN163L (Imetelstat, IND# 170891, NSC# 754228) in Combination with Fludarabine and Cytarabine for Patients with Acute Myeloid Leukemia That Is in Second or Greater Relapse or That Is Refractory to Relapse Therapy; Myelodysplastic Syndrome or Juvenile Myelomonocytic Leukemia in First or Greater Relapse or Is Refractory to Relapse Therapy (Version Date 03/11/25)

XII. Continuing Review

PEPN2411, DT2216 in combination with irinotecan for children, adolescents and young adults with relapsed or refractory solid tumors: a phase 1 study with phase 2 feasibility cohort for fibrolamellar carcinoma (Version Date 11/25/24)
