

Pediatric CIRB Meeting Agenda

August 13, 2026

I. Amendment Review

PEPN2011, A Phase 1/2 Study of Tegavivint (IND#156033, NSC#826393) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors, Including Lymphomas and Desmoid Tumors (Version Date 06/22/26)

II. 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)

III. Amendment 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 06/17/26)

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 07/13/26)

V. 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 05/08/26)

VI. Continuing Review

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

VII. 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 04/29/26)

VIII. 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 10/31/25)

IX. 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)

X. Amendment Review

ANBL2421, Phase 1/2 Study of Dinutuximab/Cyclophosphamide/Topotecan/Sargramostim (GM-CSF) with or without Iberdomide in Children with Relapsed, Refractory, or Progressive Neuroblastoma Following Prior Chemoimmunotherapy (Version Date 07/17/26)
