

Pediatric CIRB Meeting Agenda

January 15, 2026

I. Continuing Review

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) (Version Date 02/26/24)

II. Continuing Review

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) (Version Date 06/05/24)

III. Continuing Review

PEPN2415, A Phase I study to assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of AZD1390 (NSC# 852149, IND# 172675) when combined with focal radiation in pediatric patients with High Grade Glioma (Version Date 03/27/25)

IV. Continuing Review

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 (Version Date 11/19/24)

V. Continuing Review

ACNS1723, A Phase 2 Study of Dabrafenib (NSC# 763760) with Trametinib (NSC# 763093) after Local Irradiation in Newly-Diagnosed BRAFV600-Mutant High-Grade Glioma (HGG) (IND# 145355) (Version Date 12/01/25)

VI. Continuing Review

ACNS1821, A Phase 1/2 Trial of Selinexor (KPT-330) and Radiation Therapy in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG) (Version Date 04/08/25)

VII. Continuing Review

AEWS2431, Randomized phase 2/3 trial of vincristine-irinotecan-regorafenib in combination with vincristine-doxorubicin-cyclophosphamide (VDC) and ifosfamide-etoposide (IE) in patients with newly diagnosed metastatic Ewing sarcoma (Version Date 04/21/25)

VIII. Continuing Review

AGCT1532, Phase 3 Accelerated BEP Trial: A randomized phase 3 trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor-risk metastatic germ cell tumors (Version Date 08/28/24)

IX. Continuing Review

APEC14B1, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Version Date 03/10/25)

X. Continuing Review

PEPN1924, A Phase 1/2 study of DS-8201a in children, adolescents, or young adults with recurrent Osteosarcoma, Wilms Tumor, and Desmoplastic Small Round Cell Tumor (Version Date 12/02/25)
