

Pediatric CIRB Meeting Agenda

March 13, 2025

I. Initial 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 02/18/25)

II. Amendment 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 02/20/25)

III. Amendment Review

ACNS1831, A Phase 3 Randomized Study of Selumetinib (IND # 77782) versus Carboplatin/Vincristine in Newly Diagnosed or Previously Untreated Neurofibromatosis Type 1 (NF1) Associated Low-Grade Glioma (LGG) (Version Date 01/10/25)

IV. 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)

V. 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)

VI. 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)

VII. 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 03/20/24)

VIII. 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 03/25/24)

IX. 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)

X. Continuing Review

APEC14B1, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Version Date 08/09/24)
