

**Pediatric CIRB Meeting Agenda**

**December 12, 2024**

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**I. Amendment**

**ANHL2121**, Phase 2 Study of Tovorafenib (DAY101) in Relapsed and Refractory Langerhans Cell Histiocytosis (Version Date 10/31/24)

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**II. 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  $\geq 1$  to  $<31$  Years Old with First Relapse (Version Date 09/19/24)

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**III. 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 11/17/23)

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**IV. 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 09/16/22)

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**V. Continuing Review**

**AHEP1531**, Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT) (Version Date 08/14/23)

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**VI. Continuing Review**

**PBTC-053**, A Pediatric Brain Tumor Consortium Phase I/II and Surgical Study of CX-4945 in Patients with Recurrent SHH Medulloblastoma (Version Date 10/10/24)

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**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 11/13/24)

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**VIII. 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)

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