



## **Pediatric CIRB Meeting Agenda**

**August 12, 2021**

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### **I. Continuing Review**

**AALL1821**, A Phase 2 Study of Blinatumomab (NSC# 765986, IND #125462) in Combination with Nivolumab (NSC# 748726, IND# 125462), a Checkpoint Inhibitor of PD-1, in B-ALL Patients Aged  $\geq 1$  to  $< 31$  Years with First Relapse (Protocol Version Date 02/10/21)

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### **II. 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 (Protocol Version Date 12/03/20)

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### **III. Continuing Review**

**ADVL1823**, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias (Protocol Version Date 02/23/21)

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### **IV. Continuing Review**

**AHEP1531**, Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT) (Protocol Version Date 07/09/21)

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### **V. Continuing Review**

**PBTC-053**, A Pediatric Brain Tumor Consortium Phase I/II and Surgical Study of CX-4945 in Patients with Recurrent SHH Medulloblastoma (Protocol Version Date 12/04/20)

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## **VI. Continuing Review**

**PEPN1812**, A Phase 1 Trial of the CD123 X CD3 DART® Molecule Flotetuzumab (NSC#808294, IND#145986) in Children, Adolescents, and Young Adults with Relapsed or Refractory Acute Myeloid Leukemia (Protocol Version Date 07/08/20)

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## **VII. New Study - Initial 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 (Protocol Version Date 06/24/21)

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## **VIII. Amendment**

**ANBL1531**, A Phase 3 Study of <sup>131</sup>I-Metaiodobenzylguanidine (<sup>131</sup>I-MIBG) or Crizotinib Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL) (IND# 134379) (Protocol Version Date 07/21/21)

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## **X. Amendment**

**AREN1721**, A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups (Protocol Version Date 07/20/21)

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