

Pediatric CIRB Meeting Agenda

June 9, 2022

I. 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 (Protocol Version Date 02/28/22)

II. Continuing Review

ACCL2031, A Phase 3 Randomized, Placebo-Controlled Trial Evaluating Memantine for Neurocognitive Protection in Children Undergoing Cranial Radiotherapy as Part of Treatment for Primary Central Nervous System Tumors (Protocol Version Date 06/07/21)

III. 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)

IV. 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)

V. Continuing Review

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

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 (Protocol Version Date 12/04/20)

VII. Patient Recruitment Material/Information Docs

APEC14B1, The Project: Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Protocol Version Date 12/10/21)

VIII. Potential Unanticipated Problem Review

PEPN2111, A Phase 1/2 Trial of CBL0137 (NSC# 825802, IND# TBD) in Patients with Relapsed or Refractory Solid Tumors including CNS Tumors and Lymphoma (Protocol Version Date 07/07/21)
