

Pediatric CIRB Meeting Agenda

September 10, 2020

I. Continuing Review

AALL1631, International Phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones (Protocol Version Date 09/30/19)

II. Continuing Review

AAML18P1, Stopping Tyrosine Kinase Inhibitors (TKI) to Assess Treatment-Free Remission (TFR) in Pediatric Chronic Myeloid Leukemia - Chronic Phase (CML-CP) (Protocol Version Date 05/07/19)

III. Continuing Review

ACNS1833, A Phase 3 Randomized Non-Inferiority Study of Carboplatin and Vincristine versus Selumetinib (NSC# 748727, IND# 77782) in Newly Diagnosed or Previously Untreated Low-Grade Glioma (LGG) not associated with BRAFV600E Mutations or Systemic Neurofibromatosis Type 1 (NF1) (Protocol Version Date 06/15/20)

IV. Continuing Review

ANBL1821, A Phase 2 Randomized Study of Irinotecan/Temozolomide/Dinutuximab with or without Eflornithine (DFMO) (IND# 141913) in Children with Relapsed, Refractory or Progressive Neuroblastoma (Protocol Version Date 06/24/20)

V. New Study - Initial 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 ≥ 1 to < 31 Years with First Relapse (Protocol Version Date 07/20/20)

VI. New Study - Initial 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 06/22/20)

VII. New Study - Initial Review

PED-CITN-02, GD2-CAR PERSIST: Production and Engineering of GD2-Targeted, Receptor Modified T Cells (GD2CART) for Sarcoma and Neuroblastoma to Increase Systemic Tumor Exposure (Protocol Version Date 08/04/20)

VIII. Amendment

ADV1414, A Phase 1 Study of Selinexor (KPT-330, IND #125052), A Selective XPO1 Inhibitor, In Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors (Protocol Version Date 07/23/20)

IX. Amendment

ANBL1531, A Phase 3 Study of ¹³¹I-Metaiodobenzylguanidine (¹³¹I-MIBG) or Crizotinib Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL) (IND# 134379) (Protocol Version Date 07/31/20)
