

Pediatric CIRB Meeting Agenda

December 10, 2020

I. Continuing 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) (Protocol Version Date 11/04/20)

II. Continuing Review

ADVL1414, 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 09/28/20)

III. Continuing Review

ADVL1615, A Phase 1 Study of Pevonedistat (MLN4924, IND # 136078), A NEDD8 Activating Enzyme (NAE) Inhibitor, in Combination with Temozolomide and Irinotecan in Pediatric Patients with Recurrent or Refractory Solid Tumors (Protocol Version Date 08/27/20)

IV. 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 (Protocol Version Date 08/30/19)

V. Continuing Review

ANBL1232, Utilizing Response- and Biology-Based Risk Factors to Guide Therapy in Patients with Non-High-Risk Neuroblastoma. A Groupwide Historically Controlled Phase III Study (Protocol Version Date 11/13/17)

VI. Continuing Review

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 09/16/20)

VII. Continuing Review

ANHL1522, A Pilot Study of Rituximab (RTX) and Third Party Latent Membrane Protein (LMP)-specific Cytotoxic T-Lymphocytes (LMP-TC, IND # 17068) in Pediatric Solid Organ Recipients (SOT) with EBV-Positive CD20-Positive Post-Transplant Lymphoproliferative Disease (PTLD) (Protocol Version Date 03/23/20)

VIII. Continuing Review

ARST1921, A Safety, Pharmacokinetic and Efficacy Study of a γ -Secretase Inhibitor, Nirogacestat (PF 03084014; IND# 146375), in Children and Adolescents with Progressive, Surgically Unresectable Desmoid Tumors (Protocol Version Date 06/29/20)

IX. Continuing Review

PBTC-056, A Phase I study of the ADAM-10 inhibitor, INCB007839 in children with recurrent/progressive high-grade gliomas to target microenvironmental neuropilin-3 (Protocol Version Date 09/24/20)

X. New Study ReReview

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 10/21/20)

XI. Amendment

ADVL1414, 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 11/10/20)

XII. Memos

AHEP1531, Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT) (Protocol Version Date 09/10/20)

XIII. Memos

PBTC-056, A Phase I study of the ADAM-10 inhibitor, INCB007839 in children with recurrent/progressive high-grade gliomas to target microenvironmental neuroligin-3 (Protocol Version Date 09/24/20)
