

Pediatric CIRB Meeting Agenda

February 13, 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 11/01/19)

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 12/24/19)

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 12/11/19)

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 Groupwise 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 09/24/19)

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 08/05/19)

VIII. Continuing Review

APEC14B1, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Protocol Version Date 06/29/17)

IX. New Study - Initial Review

AAML1831, A Phase 3 Randomized Trial for Patients with De Novo AML Comparing Standard Therapy Including Gemtuzumab Ozogamicin (GO) to CPX-351 with GO, and the Addition of the FLT3 Inhibitor Gilteritinib for Patients with FLT3 Mutations (Protocol Version Date 01/15/20)

X. New Study - Initial Review

PED-CITN-01, 3CI Study: Childhood Cancer Combination Immunotherapy. Phase 1b and Expansion Study of Nivolumab Combination Immunotherapy in Children, Adolescent and Young Adult (CAYA) Patients with Relapsed/Refractory Hypermutant Cancers (Protocol Version Date 12/28/19)

XI. Amendment

ADV11712, A Feasibility Trial of MLN4924 (Pevonedistat, TAK 924) Given in Combination with Azacitidine, Fludarabine, and Cytarabine, in Children, Adolescents, and Young Adults with Relapsed or Refractory Acute Myeloid Leukemia or Relapsed Myelodysplastic Syndrome (Protocol Version Date 12/27/19)

XII. Amendment

PBTC-049, A Phase I study of Savolitinib in Recurrent, Progressive or Refractory Medulloblastoma, High-Grade Glioma, Diffuse Intrinsic Pontine Glioma and CNS tumors harboring MET aberrations. (Protocol Version Date 12/11/19)
