

Pediatric CIRB Meeting Agenda

August 11, 2022

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 04/07/21)

II. 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)

III. Continuing Review

ANBL1531, A Phase 3 Study of ¹³¹I-Metaiodobenzylguanidine (¹³¹I-MIBG) or ALK Inhibitor Therapy Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL) (IND# 134379) (Protocol Version Date 01/14/22)

IV. 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)

V. 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 Neuroligin-3 (Protocol Version Date 05/27/21)

VI. Continuing Review

PED-CITN-02, GD2-CAR PERSIST: Production and Engineering of GD2-Targeted, Receptor Modified T Cells (GD2CART) for Osteosarcoma and Neuroblastoma to Increase Systemic Tumor Exposure (Protocol Version Date 08/20/21)

VII. Continuing Review

PEPN1924, A Phase 2 Study of DS-8201A (NSC# 807708, IND# 153036) in Adolescents, or Young Adults with Recurrent HER2+ Osteosarcoma (Protocol Version Date 12/22/21)

VIII. New Study - Initial Review

ANHL2121, Phase 2 Study of DAY101 in Relapsed and Refractory Langerhans Cell Histiocytosis (Protocol Version Date 07/15/22)

IX. New Study - Initial Review

ARET2121, Intravitreal Melphalan for Intraocular Retinoblastoma (Protocol Version Date 07/12/22)

X. Potential Unanticipated Problem and Serious and/or Continuing Noncompliance 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 04/26/22)
