

Pediatric CIRB Meeting Agenda

January 9, 2020

I. Continuing Review

ADVL1513, A Phase 1 Study of Entinostat, An Oral Histone Deacetylase Inhibitor, In Pediatric Patients with Recurrent or Refractory Solid Tumors, Including CNS Tumors and Lymphoma (Protocol Version Date 01/31/19)

II. Continuing Review

ADVL1521, A Phase 2 Study of the MEK inhibitor Trametinib (IND #119346, NSC# 763093) in Children with Relapsed or Refractory Juvenile Myelomonocytic Leukemia (Protocol Version Date 12/10/19)

III. Continuing Review

ADVL1712, 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 09/24/19)

IV. New Study ReReview

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 12/20/19)

V. New Study - Initial Review

PBTC-056, A Phase I study of the ADAM-10 inhibitor, INCB7839 in children with recurrent/progressive high-grade gliomas to target microenvironmental neuroligin-3 (Protocol Version Date 12/12/19)

VI. Amendment

ADV11615, 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)

VII. Amendment

AREN1721, A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Axitinib or Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups (Protocol Version Date 11/27/19)

VIII. Memos

AREN03B2, Renal Tumors Classification, Biology, and Banking Study (Protocol Version Date 04/25/14)

IX. Memos

PBTC-051, Phase I Study to Evaluate the Safety and Tolerability of the CD40 Agonistic Monoclonal Antibody APX005M in Pediatric Subjects with Recurrent/Refractory Brain Tumors and Newly Diagnosed Brain Stem Glioma (Protocol Version Date 09/27/18)
