

Pediatric CIRB Meeting Agenda

November 12, 2020

I. Continuing Review

ADV1513, 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

ADV1521, 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 10/20/20)

III. Continuing Review

ADV1712, A Feasibility Trial of MLN4924 (Pevonedistat, TAK 924, IND#142772) Given in Combination with Azacitidine, Fludarabine, and Cytarabine, in Children, Adolescents, and Young Adults with Relapsed or Refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome (Protocol Version Date 08/27/20)

IV. Continuing Review

ADV18P1, An Open-Label Feasibility Study to Assess the Safety and Pharmacokinetics of Enasidenib in Pediatric Patients with Relapsed/Refractory Acute Myeloid Leukemia (R/R-AML) with an Isocitrate Dehydrogenase-2 (IDH2) Mutation (Protocol Version Date 02/11/20)

V. New Study - Initial Review

PEPN1924, A PHASE 2 STUDY OF DS-8201A (NSC# 807708, IND# TBD) IN ADOLESCENTS, OR YOUNG ADULTS WITH RECURRENT HER2+ OSTEOSARCOMA (Protocol Version Date 09/28/20)

VI. Amendment

AALL1621, A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND#133494) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL) (Protocol Version Date 09/16/20)

VII. Amendment

ACNS1723, A Phase 2 Study of Dabrafenib (NSC# 763760) with Trametinib (NSC# 763093) after Local Irradiation in Newly-Diagnosed BRAFV600-Mutant High-Grade Glioma (HGG) (IND# 145355) (Protocol Version Date 09/28/20)

VIII. Unanticipated Problem and Serious and/or Continuing Noncompliance Review

AAML1031, A Phase III Randomized Trial for Patients with de novo AML using Bortezomib and Sorafenib (IND#114480; NSC# 681239, NSC# 724772) for Patients with High Allelic Ratio FLT3/ITD (Protocol Version Date 04/24/17)

AALL1131, A Phase III Randomized Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Including a Stratum Evaluating Dasatinib (IND#73789, NSC#732517) in Patients with Ph-like Tyrosine Kinase Inhibitor (TKI) Sensitive Mutations (Protocol Version Date 12/28/18)

AALL0932, Treatment of Patients with Newly Diagnosed Standard Risk B-Lymphoblastic Leukemia (B-ALL) or Localized B-lineage Lymphoblastic Lymphoma (B-LLy) (Protocol Version Date 10/26/17)

IX. Unanticipated Problem and Serious and/or Continuing Noncompliance

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 09/28/20)
