

Pediatric CIRB Meeting Agenda

July 14, 2022

I. 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 10/20/20)

II. New Study - Initial Review

ACNS2031, A Phase 3 Study of Sodium Thiosulfate for Reduction of Cisplatin-Induced Ototoxicity in Children with Average-Risk Medulloblastoma and Reduced Therapy in Children with Medulloblastoma with Low-Risk Features (Protocol Version Date 05/27/22)

III. Amendment Review

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 05/26/22)

IV. Potential Unanticipated Problem 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)
