

## **Pediatric CIRB Meeting Agenda**

**September 9, 2021**

---

### **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. Continuing Review**

**ADVL18P1**, 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)

---

### **III. Amendment**

**AALL1732**, A Phase 3 Randomized Trial of Inotuzumab Ozogamicin (IND#:133494, NSC#: 772518) for Newly Diagnosed High-Risk B-ALL; Risk-Adapted Post-Induction Therapy for High-Risk B-ALL, Mixed Phenotype Acute Leukemia, and Disseminated B-LLy (Protocol Version Date 07/15/21)

---

### **IV. Potential Unanticipated Problem and Serious and/or Continuing Noncompliance Review**

**PEPN1812**, A Phase 1 Trial of the CD123 X CD3 DART® Molecule Flotetuzumab (NSC#808294, IND#145986) in Children, Adolescents, and Young Adults with Relapsed or Refractory Acute Myeloid Leukemia (Protocol Version Date 07/08/20)

---

### **V. Amendment Re-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 08/31/21)

---