

Pediatric CIRB Meeting Agenda

May 13, 2021

I. Continuing Review

ACCL1633, The Effectiveness of Lactobacillus plantarum (LBP, IND #17339) In preventing Acute Graft-versus-Host Disease (GvHD) in Children undergoing Alternative Hematopoietic Progenitor Cell Transplantation (HCT) (Protocol Version Date 04/19/21)

II. Continuing Review

PED-CITN-01, 3CI Study: Childhood Cancer Combination Immunotherapy. Phase 1b and Expansion Study of Nivolumab Combination Immunotherapy in Children, Adolescent and Young Adult (CAYA) Patients with Relapsed/Refractory Hypermutant Cancers (Protocol Version Date 02/19/21)

III. New Study - Initial Review

ACCL20N1CD, Financial Distress during Treatment for Pediatric Acute Lymphoblastic Leukemia in the United States (Protocol Version Date 04/05/21)

IV. New Study - Initial Review

PEPN2011, A Phase 1/2 Study of Tegavivint (IND#TBD, NSC#826393) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors, Including Lymphomas and Desmoid Tumors (Protocol Version Date 03/16/21)

V. New Study - Initial Review

PEPN2111, A Phase 1/2 Trial of CBL0137 (NSC# 825802, IND# TBD) in Patients with Relapsed or Refractory Solid Tumors including CNS Tumors and Lymphoma (Protocol Version Date 03/24/21)

VI. Amendment

PBTC-056, A Phase I study of the ADAM-10 inhibitor, INCB007839 in children with recurrent/progressive high-grade gliomas to target microenvironmental neuropilin-3 (Protocol Version Date 03/30/21)

VII. Amendment

PBTC-058, Phase 2 Study of Intraventricular Omburtamab-based Radioimmunotherapy for Pediatric Patients with Recurrent Medulloblastoma and Ependymoma (Protocol Version Date 04/05/21)
