



Pediatric CIRB Meeting Agenda

April 14, 2022

I. Continuing Review

AALL08B1, Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL)
(Protocol Version Date 03/13/18)

II. Continuing Review

ACNS1422, A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients (Protocol Version Date 10/07/19)

III. Continuing Review

PBTC-055, Phase I/II trial of Dabrafenib, Trametinib, and Hydroxychloroquine (HCQ) for BRAF V600E-mutant or Trametinib and HCQ for BRAF fusion/duplication positive or NF1-associated recurrent or progressive gliomas in children and young adults (Protocol Version Date 05/05/21)

IV. Continuing 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 07/07/21)

V. New Study - Initial Review

APAL2020B, A PedAL/EuPAL Phase 1/2 trial of IMG632 in Pediatric Patients with Relapsed or Refractory Leukemia (Protocol Version Date 02/22/22)

VI. New Study - Initial Review

PEPN2121, A Phase 2 Study of Tiragolumab (NSC# 827799) and Atezolizumab (NSC# 783608) in Patients with Relapsed or Refractory SMARCB1 or SMARCA4 Deficient Tumors (Protocol Version Date 02/07/22)

VII. Amendment

PED-CITN-03, Phase 1 Trial of Hu5F9-G4 (Magrolimab) Combined with Dinutuximab in Children and Young Adults with Relapsed and Refractory Neuroblastoma or Relapsed Osteosarcoma (Protocol Version Date 03/17/22)

VIII. Potential Unanticipated Problem 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 01/12/22)

IX. Potential Unanticipated Problem Review

PBTC-056, A Phase I Study of the ADAM-10 inhibitor, INCB007839 in Children with Recurrent/Progressive High-Grade Gliomas to Target Microenvironmental Neuroligin-3 (Protocol Version Date 05/27/21)
