

Pediatric CIRB Meeting Agenda

October 10, 2024

I. Amendment Prior to Activation

AALL2321, A Phase 2 Study of Blinatumomab in Combination with Chemotherapy for Infants with Newly Diagnosed Acute Lymphoblastic Leukemia with Randomization of KMT2A-Rearranged Patients to Addition of Venetoclax (Version Date 09/03/24)

II. Continuing Review

AALL2121, A Phase 2 study of revumenib (SNDX-5613) in combination with chemotherapy for patients with relapsed or refractory KMT2A-rearranged infant leukemia (Version Date 06/21/24)

III. Continuing Review

ACNS1422, A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients (Version Date 02/02/23)

IV. Continuing Review

ARST2032, A Prospective Phase 3 Study of Patients with Newly Diagnosed Very Low-risk and Low-risk Fusion Negative Rhabdomyosarcoma (Version Date 12/05/22)

V. 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 (Version Date 03/14/24)

VI. Continuing Review

PEPN2111, A Phase 1/2 Trial of CBL0137 (NSC# 825802, IND# 155843) in Patients with Relapsed or Refractory Solid Tumors including CNS Tumors and Lymphoma (Version Date 5/1/2023)

VII. 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 (Version Date)
