

Pediatric CIRB Meeting Agenda

August 14, 2025

I. 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)

II. 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 03/26/25)

III. Initial Review

PBTC-062, Phase 2 Open-Label Single-Arm Trial of Laser Interstitial Thermal Therapy (LITT) for Pediatric Patients with Newly Diagnosed or Recurrent Low-Grade Glioma (LGG) (Version Date 06/09/25)

IV. Amendment

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)

V. 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 06/23/25)

VI. Continuing Review

ACCL1932, Letermovir Prophylaxis for Cytomegalovirus in Pediatric Hematopoietic Cell Transplantation (Version Date 03/20/25)

VII. 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 01/31/25)
