

Pediatric CIRB Meeting Agenda

April 11, 2024

I. Initial Review

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 02/13/24)

II. Amendment

ANHL1931, A Randomized Phase 3 trial of Nivolumab(NSC# 748726 IND# 125462) in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma (Version Date 01/30/24)

III. 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 (Version Date 11/02/22)

IV. Continuing Review

ARET2121, Intravitreal Melphalan for Intraocular Retinoblastoma (Version Date 08/26/22)

V. Continuing Review

PBTC-N14, CSF Cell-free Tumor DNA (CSF cfDNA) Liquid Biopsies for Pediatric, Adolescent, and Young Adult Patients with Primary Brain Tumors (Version Date 10/04/23)

VI. Continuing Review

PED-CITN-02, GD2-CAR PERSIST: Production and Engineering of GD2-Targeted, Receptor Modified T Cells (GD2CART) for Osteosarcoma or Neuroblastoma to Increase Systemic Tumor Exposure (Version Date 12/19/23)

VII. Continuing Review

PEPN1924, A Phase 2 Study of DS-8201A (NSC# 807708, IND# 153036) in Adolescents, or Young Adults with Recurrent HER2+ Osteosarcoma (Version Date 12/22/21)

VIII. Continuing Review

PEPN2113, A Phase 1 and pharmacokinetic study of Uproleselan (GMI-1271, IND #139758, NSC #801708) in combination with fludarabine and cytarabine for patients with acute myeloid leukemia, myelodysplastic syndrome or mixed phenotype acute leukemia that expresses E-selectin ligand on the cell membrane and is in second or greater relapse or that is refractory to relapse therapy (Version Date 05/01/23)

IX. Unanticipated Problem Review

PBTC-051, Phase I Study to Evaluate the Safety and Tolerability of the CD40 Agonistic Monoclonal Antibody APX005M in Pediatric Subjects with Recurrent/Refractory Brain Tumors and Newly Diagnosed Brain Stem Glioma (Version Date)
