

Pediatric CIRB Meeting Agenda

April 13, 2023

I New Study - Initial 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 02/14/23)

II Amendment

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 02/07/23)

III Amendment

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 02/15/23)

IV Continuing Review

AALL1821, A Phase 2 Study of Blinatumomab (NSC# 765986, IND #147294) in Combination with Nivolumab (NSC# 748726, IND# 147294), a Checkpoint Inhibitor of PD-1, in B-ALL Patients Aged ≥ 1 to <31 Years Old with First Relapse (Version Date 02/28/22)

V Continuing Review

ACCL2031, A Phase 3 Randomized, Placebo-Controlled Trial Evaluating Memantine (IND #149832) for Neurocognitive Protection in Children Undergoing Cranial Radiotherapy as Part of Treatment for Primary Central Nervous System Tumors (Version Date 06/07/21)

VI Continuing Review

ACNS1931, A Phase 3 Study of Selumetinib (NSC# 748727, IND# 77782) or Selumetinib in Combination with Vinblastine for non-NF1, non-TSC Patients with Recurrent or Progressive Low-Grade Gliomas (LGGs) Lacking BRAFV600E or IDH1 Mutations (Version Date 09/16/22)

VII Continuing Review

ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias (Version Date 10/13/22)

VIII Continuing Review

AHEP1531, Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT) (Version Date 07/09/21)

IX Continuing Review

PBTC-053, A Pediatric Brain Tumor Consortium Phase I/II and Surgical Study of CX-4945 in Patients with Recurrent SHH Medulloblastoma (Version Date 11/17/22)

X **Continuing Review**

PBTC-060, A Pilot Study of Safety, Tolerability, and Immunological Effects of SurVaxM in Pediatric Patients with Progressive or Relapsed Medulloblastoma, High Grade Glioma, Ependymoma and Newly Diagnosed Diffuse Intrinsic Pontine Glioma (Version Date 04/29/22)

XI **Continuing Review**

PEPN22P1, A Pharmacokinetic Study of VinCRISTine in Infants Dosed According to BSA-Banded Infant Dosing Tables (Version Date 05/31/22)
