

Pediatric CIRB Meeting Agenda

October 8, 2020

I. Continuing Review

AALL0932, Treatment of Patients with Newly Diagnosed Standard Risk B-Lymphoblastic Leukemia (B-ALL) or Localized B-lineage Lymphoblastic Lymphoma (B-LLy) (Protocol Version Date 10/26/17)

II. Continuing Review

ADVL1412, A Phase 1/2 Study of Nivolumab (IND# 124729) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab (Protocol Version Date 03/30/20)

III. 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 (Protocol Version Date 05/05/20)

IV. Continuing Review

AHEP1531, Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT) (Protocol Version Date 09/10/20)

V. Continuing Review

ANHL12P1, A Randomized Phase II Trial of Brentuximab Vedotin (SGN35, NSC# 749710) or Crizotinib (NSC#749005, commercially labeled) in Combination with Chemotherapy for Newly Diagnosed Patients with Anaplastic Large Cell Lymphoma (ALCL) IND # 117117 (Protocol Version Date 02/01/19)

VI. Continuing Review

PBTC-053, A Pediatric Brain Tumor Consortium Phase I/II and Surgical Study of CX-4945 in Patients with Recurrent SHH Medulloblastoma (Protocol Version Date 02/17/20)

VII. Continuing Review

PEPN1812, A Phase 1 Trial of the CD123 X CD3 DART® Molecule Flotetuzumab (NSC#808294, IND#145986) in Children, Adolescents, and Young Adults with Relapsed or Refractory Acute Myeloid Leukemia (Protocol Version Date 07/08/20)

VIII. New Study - Initial 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 (Protocol Version Date 08/12/20)

IX. Amendment

AALL1732, A Phase 3 Randomized Trial of Inotuzumab Ozogamicin (IND#:133494, NSC#: 772518) for Newly Diagnosed High-Risk B-ALL; Risk-Adapted Post-Induction Therapy for High-Risk B-ALL, Mixed Phenotype Acute Leukemia, and Disseminated B-LLy (Protocol Version Date 08/26/20)

X. Amendment

AGCT1531, A Phase 3 Study of Active Surveillance for Low risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors (Protocol Version Date 08/19/20)
