

Pediatric CIRB Meeting Agenda

April 9, 2020

I. Continuing Review

AALL15P1, A Groupwide Pilot Study to Test the Tolerability and Biologic Activity of the Addition of Azacitidine (IND# 133688, NSC# 102816) to Chemotherapy in Infants with Acute Lymphoblastic Leukemia (ALL) and KMT2A (MLL) Gene Rearrangement (Protocol Version Date 09/25/19)

II. Continuing Review

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 08/22/19)

III. Continuing Review

ACNS1721, A Phase 2 Study of Veliparib (ABT-888, IND # 139199) and Local Irradiation, Followed by Maintenance Veliparib and Temozolomide, in Patients with Newly Diagnosed High-Grade Glioma (HGG) without H3 K27M or BRAFV600 Mutations (Protocol Version Date 03/04/20)

IV. Continuing Review

ADVL1514, A Phase 1 Study of ABI-009 (nab-Rapamycin) (IND# 133537) in Pediatric Patients with Recurrent or Refractory Solid Tumors, Including CNS Tumors as a Single Agent and in Combination with Temozolomide and Irinotecan (Protocol Version Date 01/31/19)

V. Continuing Review

ALTE1621, Pharmacologic Reversal of Ventricular Remodeling in Childhood Cancer Survivors at Risk for Heart Failure (PREVENT-HF): A Phase 2b Randomized Placebo-Controlled (Carvedilol) Trial (Protocol Version Date 01/02/20)

VI. Continuing 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 (Protocol Version Date 02/21/20)

VII. New Study - Initial Review

ALTE2031, StepByStep: A Randomized Trial of a Mobile Health and Social Media Physical Activity Intervention among Adolescent and Young Adult Childhood Cancer Survivors (Protocol Version Date 02/24/20)

VIII. New Study - Initial Review

APEC1621N, NCI-COG Pediatric Molecular Analysis for Therapy Choice MATCH – Phase 2 Subprotocol of LOXO-292 in Patients with Tumors Harboring RET Gene Alterations (Protocol Version Date 02/18/20)

IX. Patient Recruitment Material/Information Docs

ALTE2031, StepByStep: A Randomized Trial of a Mobile Health and Social Media Physical Activity Intervention among Adolescent and Young Adult Childhood Cancer Survivors (Protocol Version Date 02/24/20)

X. Potential Unanticipated Problem and Serious and/or Continuing Noncompliance Review

ANBL1821, A Phase 2 Randomized Study of Irinotecan/Temozolomide/Dinutuximab with or without Eflornithine (DFMO) (IND# 141913) in Children with Relapsed, Refractory or Progressive Neuroblastoma (Protocol Version Date 06/19/19)
