

Pediatric CIRB Meeting Agenda

June 11, 2020

I. Continuing Review

ADVL1614, A Phase 1/2 Study of VX15/2503 (IND #136181) in Children, Adolescents, or Young Adults with Recurrent or Relapsed Solid Tumors (Protocol Version Date 01/31/19)

II. Continuing Review

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 07/10/19)

III. Continuing Review

APEC1621A, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 Subprotocol of LOXO-101 (Larotrectinib) in Patients with Tumors Harboring Actionable NTRK Fusions (Protocol Version Date 10/07/19)

IV. Continuing Review

APEC1621B, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 subprotocol of JNJ-42756493 (Erdafitinib) in patients with tumors harboring FGFR1/2/3/4 alterations (Protocol Version Date 03/08/19)

V. Continuing Review

APEC1621C, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 subprotocol of tazemetostat for patients with tumors harboring alterations in EZH2 or members of the SWI/SNF complex (Protocol Version Date 03/21/19)

VI. Continuing Review

APEC1621D, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 subprotocol of LY3023414 in Patients with Solid Tumors (Protocol Version Date 02/18/20)

VII. Continuing Review

APEC1621E, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)– Phase 2 subprotocol of Selumetinib (AZD6244 Hydrogen Sulfate) in patients with Tumors harboring activating MAPK pathway mutations (Protocol Version Date 08/19/19)

VIII. Continuing Review

APEC1621F, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)– Phase 2 Subprotocol of Ensartinib in Patients with Tumors harboring ALK or ROS1 Genomic Alterations (Protocol Version Date 03/24/20)

IX. Continuing Review

APEC1621G, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 subprotocol of Vemurafenib in patients with tumors harboring BRAF V600 mutations (Protocol Version Date 03/30/20)

X. Continuing Review

APEC1621H, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 Subprotocol of Olaparib in Patients with Tumors Harboring Defects in DNA Damage Repair Genes (Protocol Version Date 05/23/19)

XI. Continuing Review

APEC1621I, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 subprotocol of Palbociclib in Patients with Tumors Harboring Activating Alterations in Cell Cycle Genes (Protocol Version Date 11/26/19)

XII. Continuing Review

APEC1621J, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 Subprotocol of BVD-523FB (ulixertinib) in Patients with Tumors Harboring Activating MAPK Pathway Mutations (Protocol Version Date 06/18/19)

XIII. Continuing Review

APEC1621K, NCI-COG Pediatric Molecular Analysis for Therapy Choice MATCH - Phase 2 subprotocol of AG-120 (ivosidenib) in Patients with Tumors harboring IDH1 mutations (Protocol Version Date 01/06/20)

XIV. Continuing Review

APEC1621M, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 subprotocol of Tipifarnib in Patients with Tumors Harboring HRAS Genomic Alterations (Protocol Version Date 03/24/20)

XV. Continuing Review

APEC1621N, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LOXO-292 in Patients Harboring RET Gene Alterations (Protocol Version Date 04/27/20)

XVI. Continuing Review

APEC1621SC, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol (Protocol Version Date 03/11/20)

XVII. New Study ReReview

ANBL19P1, A Pilot Study of Dinutuximab, Sargramostim (GM-CSF), and Isotretinoin in Combination with Irinotecan and Temozolomide in the Post-Consolidation Setting for High-Risk Neuroblastoma (Protocol Version Date 06/01/20)

XVIII. Amendment

AALL1731, A Phase 3 Trial Investigating Blinatumomab (IND# 117467, NSC# 765986) in Combination with Chemotherapy in Patients with Newly Diagnosed Standard Risk or Down syndrome B-Lymphoblastic Leukemia (B-ALL) and the Treatment of Patients with Localized B-Lymphoblastic Lymphoma (B-LLy) (Protocol Version Date 03/30/20)

XIX. Amendment

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 05/05/20)

XX. Amendment

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 05/15/20)
