

Pediatric CIRB Meeting Agenda

April 8, 2021

I. 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 10/26/20)

II. Continuing Review

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 07/15/20)

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 07/20/20)



VI. Continuing Review

APEC1621D, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) -Phase 2 subprotocol of LY3023414 in Patient with Solid Tumors (Protocol Version Date 03/12/21)

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 08/12/20)

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 11/10/20)

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 12/9/20)

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 09/28/20)

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 12/11/20)

XV. Continuing Review

APEC1621N, NCI-COG Pediatric Molecular Analysis for Therapy Choice (MATCH) – Phase 2 Subprotocol of LOXO-292 in Patients Harboring RET Gene Alterations (Protocol Version Date 10/23/20)

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

ACNS2021, A Phase 2 Trial of Chemotherapy followed by Response-Based Whole Ventricular & Spinal Canal Irradiation (WVSCI) for Patients with Localized Non-Germinomatous Central Nervous System Germ Cell Tumor (Protocol Version Date 03/10/21)