

Pediatric CIRB Meeting Agenda

November 9, 2023

I. Continuing Review

AHOD2131, A Randomized Phase 3 Interim Response Adapted Trial Comparing Standard Therapy with Immuno-oncology Therapy for Children and Adults with Newly Diagnosed Stage I and II Classic Hodgkin Lymphoma (Version Date 08/21/23)

II. Initial Review

AALL2131, A Randomized International Phase 3 Trial of Dasatinib and Chemotherapy with or without Blinatumomab in Patients with Newly-Diagnosed Philadelphia Chromosome Positive or Philadelphia Chromosome-Like ABL-class B-cell Acute Lymphoblastic Leukemia (Version Date 10/12/23)

III. Initial Review

ANBL2131, A Phase 3 Study of Dinutuximab Added to Intensive Multimodal Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (Version Date 09/22/23)

IV. Amendment

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 07/31/23)

V. Amendment

ACNS1723, A Phase 2 Study of Dabrafenib (NSC# 763760) with Trametinib (NSC# 763093) after Local Irradiation in Newly-Diagnosed BRAFV600-Mutant High-Grade Glioma (HGG) (IND# 145355) (Version Date 09/15/23)

VI. Continuing Review

APEC1621SC **DO NOT USE OR SUBMIT WORKSHEETS**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol (Version Date 10/28/22)

VII. Continuing Review

APEC1621A **DO NOT USE OR SUBMIT WORKSHEETS**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 Subprotocol of LOXO-101 (Larotrectinib) in Patients with Tumors Harboring Actionable NTRK Fusions (Version Date 10/28/22)

VIII. Continuing Review

APEC1621B **DO NOT USE OR SUBMIT WORKSHEETS**, 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 (Version Date 10/28/22)

IX. Continuing Review

APEC1621C **DO NOT USE OR SUBMIT WORKSHEETS**, 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 (Version Date 06/15/21)

X. Continuing Review

APEC1621D **DO NOT USE OR SUBMIT WORKSHEETS**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 subprotocol of LY3023414 in Patient with Solid Tumors (Version Date 10/28/22)

XI. Continuing Review

APEC1621E **DO NOT USE OR SUBMIT WORKSHEETS**, 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 (Version Date 08/19/19)

XII. Continuing Review

APEC1621F **DO NOT USE OR SUBMIT WORKSHEETS**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)– Phase 2 Subprotocol of Ensartinib in Patients with Tumors harboring ALK or ROS1 Genomic Alterations (Version Date 10/28/22)

XIII. Continuing Review

APEC1621G **DO NOT USE OR SUBMIT WORKSHEETS**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 subprotocol of Vemurafenib in patients with tumors harboring BRAF V600 mutations (Version Date 11/10/20)

XIV. Continuing Review

APEC1621H **DO NOT USE OR SUBMIT WORKSHEETS**, 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 (Version Date 09/09/21)

XV. Continuing Review

APEC1621I **DO NOT USE OR SUBMIT WORKSHEETS**, 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 (Version Date 11/30/21)

XVI. Continuing Review

APEC1621J **DO NOT USE OR SUBMIT WORKSHEETS**, 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 (Version Date 12/09/20)

XVII. Continuing Review

APEC1621K **DO NOT USE OR SUBMIT WORKSHEETS**, NCI-COG Pediatric Molecular Analysis for Therapy Choice MATCH - Phase 2 subprotocol of AG-120 (ivosidenib) in Patients with Tumors harboring IDH1 mutations (Version Date 10/28/22)

XVIII. Continuing Review

APEC1621M **DO NOT USE OR SUBMIT WORKSHEETS**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 subprotocol of Tipifarnib in Patients with Tumors Harboring HRAS Genomic Alterations (Version Date 10/28/22)

XIX. Continuing Review

APEC1621N **DO NOT USE OR SUBMIT WORKSHEETS, NCI-COG
Pediatric Molecular Analysis for Therapy Choice (MATCH) – Phase 2
Subprotocol of LOXO-292 in Patients Harboring RET Gene Alterations (Version
Date 10/28/22)**
