

Pediatric CIRB Meeting Agenda

January 12, 2023

I Potential Unanticipated Problem Review

AALL1821, A Phase 2 Study of Blinatumomab (NSC# 765986, IND #147294) in Combination with Nivolumab (NSC# 748726, IND# 147294), a Checkpoint Inhibitor of PD-1, in B-ALL Patients Aged ≥ 1 to <31 Years Old with First Relapse (Version Date 02/28/22)

II Potential Unanticipated Problem Review

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) (Version Date 10/11/22)

III New Study - Initial Review

ACCL1932, Letermovir Prophylaxis for Cytomegalovirus in Pediatric Hematopoietic Cell Transplantation (Version Date 10/10/22)

IV Continuing Review

APEC1621SC, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol (Version Date 10/28/22)

V 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 (Version Date 10/28/22)

VI 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 (Version Date 10/28/22)

VII 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 (Version Date 06/15/21)

VIII Continuing Review

APEC1621D, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 subprotocol of LY3023414 in Patient with Solid Tumors (Version Date 10/28/22)

IX 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 (Version Date 08/19/19)

X 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 (Version Date 10/28/22)

XI 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 (Version Date 11/10/20)

XII 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 (Version Date 09/09/21)

XIII 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 (Version Date 11/30/21)

XIV 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 (Version Date 12/09/20)

XV 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 (Version Date 10/28/22)

XVI 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 (Version Date 10/28/22)

XVII Continuing Review

APEC1621N, 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)

XVIII Potential Unanticipated Problem Review

PBTC-058, Phase 2 Study of Intraventricular Omburtamab-based Radioimmunotherapy for Pediatric Patients with Recurrent Medulloblastoma and Ependymoma (Version Date 06/10/22)

XIX New Study - Initial 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 11/10/22)
