



Pediatric CIRB Meeting Agenda

March 10, 2022

I. Continuing Review

ACCL1633, The Effectiveness of *Lactobacillus plantarum* (LBP, IND #17339) In preventing Acute Graft-versus-Host Disease (GvHD) in Children undergoing Alternative Hematopoietic Progenitor Cell Transplantation (HCT) (Protocol Version Date 04/19/21)

II. 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 11/18/21)

III. 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)

IV. 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 06/15/21)

V. 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 11/18/21)

VI. 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)

VII. 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 01/13/22)

VIII. 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)

IX. 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 09/09/21)

X. 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 11/30/21)

XI. 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 12/09/20)

XII. 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 11/30/21)

XIII. 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 12/23/21)

XIV. 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)

XV. Continuing Review

APEC1621SC, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol (Protocol Version Date 11/18/21)

XVI. Continuing Review

PED-CITN-01, 3CI Study: Childhood Cancer Combination Immunotherapy. Phase 1b and Expansion Study of Nivolumab Combination Immunotherapy in Children, Adolescent and Young Adult (CAYA) Patients with Relapsed/Refractory Hypermutant Cancers (Protocol Version Date 07/06/21)

XVII. New Study - Initial Review

ARST2032, A Prospective Phase 3 Study of Patients with Newly Diagnosed Very Low-risk and Low-risk Fusion Negative Rhabdomyosarcoma (Protocol Version Date 01/16/22)

XVIII. Amendment

PED-CITN-03, Phase 1 Trial of Hu5F9-G4 (Magrolimab) Combined with Dinutuximab in Children and Young Adults with Relapsed and Refractory Neuroblastoma or Relapsed Osteosarcoma (Protocol Version Date 02/07/22)

XIX. Unanticipated Problem

ACCL1633, The Effectiveness of Lactobacillus plantarum (LBP, IND #17339) In preventing Acute Graft-versus-Host Disease (GvHD) in Children undergoing Alternative Hematopoietic Progenitor Cell Transplantation (HCT) (Protocol Version Date 04/19/21)
