

Pediatric CIRB Meeting Agenda

November 14, 2024

I. Initial Review

ACCL2433, Risk-Based 6MP Adherence Enhancement Strategies in Children, Adolescent and Young Adults with ALL – A Pilot Study (Version Date 09/19/24)

II. Initial Review

ARAR2331, Prospective Treatment of Types I, II and III Pleuropulmonary Blastoma (PPB) (Version Date 09/16/24)

III. Amendment

AAML1831, A Phase 3 Randomized Trial for Patients with De Novo AML Comparing Standard Therapy Including Gemtuzumab Ozogamicin (GO) to CPX-351 with GO, and the Addition of the FLT3 Inhibitor Gilteritinib for Patients with FLT3 Mutations (Version Date 09/30/24)

IV. Continuing Review

PBTC-059, Phase 1 Trial of Autologous HER2-specific CAR T cells in Pediatric Patients with Refractory or Recurrent Ependymoma (Version Date 12/20/23)

V. Amendment

PBTC-059, Phase 1 Trial of Autologous HER2-specific CAR T cells in Pediatric Patients with Refractory or Recurrent Ependymoma (Version Date 09/20/24)

VI. Continuing Review

AALL1631, International Phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones (Version Date 09/16/22)

VII. Continuing Review

AAML18P1, Stopping Tyrosine Kinase Inhibitors (TKI) to Assess Treatment-Free Remission (TFR) in Pediatric Chronic Myeloid Leukemia - Chronic Phase (CML-CP) (Version Date 10/06/20)

VIII. Continuing Review

ACNS1833, A Phase 3 Randomized Non-Inferiority Study of Carboplatin and Vincristine versus Selumetinib (NSC# 748727, IND# 77782) in Newly Diagnosed or Previously Untreated Low-Grade Glioma (LGG) not associated with BRAFV600E Mutations or Systemic Neurofibromatosis Type 1 (NF1) (Version Date 09/16/22)

IX. Continuing Review

ARST2031, A Randomized Phase 3 Trial of Vinorelbine, Dactinomycin, and Cyclophosphamide (VINO-AC) Plus Maintenance Chemotherapy with Vinorelbine and Oral Cyclophosphamide (VINO-CPO) vs Vincristine, Dactinomycin and Cyclophosphamide (VAC) plus VINO-CPO Maintenance in Patients with High Risk Rhabdomyosarcoma (HR-RMS) (Version Date 07/19/24)

X. Continuing Review

PEPN2011, A Phase 1/2 Study of Tegavivint (IND#156033, NSC#826393) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors, Including Lymphomas and Desmoid Tumors (Version Date 02/13/23)

XI. Continuing Review

PEPN2121, A Phase 1/2 Study of Tiragolumab (NSC# 827799, IND# 161266) and Atezolizumab (NSC# 783608, IND# 161266) in Patients with Relapsed or Refractory SMARCB1 or SMARCA4 Deficient Tumors (Version Date 06/24/24)

XII. Potential Serious Noncompliance

APEC14B1, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Version Date 09/13/22)
