

**Pediatric CIRB Meeting Agenda**

**March 9, 2023**

**I 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 01/23/23)

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**II 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)

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**III 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)

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**IV 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)

**V Continuing Review**

**ANBL1821**, A Phase 2 Randomized Study of Irinotecan/Temozolomide/Dinutuximab with or without Eflornithine (DFMO) (IND# 141913) in Children with Relapsed, Refractory or Progressive Neuroblastoma (Version Date 06/22/21)

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**VI 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 06/10/22)

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**VII Continuing Review**

**PBTC-059**, Phase 1 Trial of Autologous HER2-specific CAR T cells in Pediatric Patients with Refractory or Recurrent Ependymoma (Version Date 01/19/23)

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**VIII 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 04/08/22)

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**IX 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 11/22/22)

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**X Potential Unanticipated Problem Review**

**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 (Version Date 11/17/21)

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**XI Potential Unanticipated Problem Review**

**ALTE05N1**, Umbrella Long-Term Follow-Up Protocol (Version Date 10/25/21)

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