

Pediatric CIRB Meeting Agenda

May 12, 2022

I 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 (Protocol Version Date 07/15/21)

II Continuing Review

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

III 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) (Protocol Version Date 04/07/21)

IV 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 (Protocol Version Date 06/22/21)

V 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) (Protocol Version Date 07/27/21)

VI 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 (Protocol Version Date 04/08/22)

VII New Study - Initial Review

PEPN22P1, A Pharmacokinetic Study of VinCRISTine in Infants Dosed According to BSA Banded Infant Dosing Tables (Protocol Version Date 04/05/22)
