

Pediatric CIRB Meeting Agenda

March 11, 2021

I. Continuing Review

AALL1131, A Phase III Randomized Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Including a Stratum Evaluating Dasatinib (IND#73789, NSC#732517) in Patients with Ph-like Tyrosine Kinase Inhibitor (TKI) Sensitive Mutations (Protocol Version Date 01/12/21)

II. Continuing Review

AAML1531, Risk-stratified Therapy for Acute Myeloid Leukemia in Down Syndrome: A COG Groupwide Phase III Study (Protocol Version Date 09/18/20)

III. Continuing Review

ANBL17P1, A Pilot Induction Regimen Incorporating Chimeric 14.18 Antibody (ch14.18, dinutuximab) (NSC# 764038, IND# 4308) and Sargramostim (GM-CSF) for the Treatment of Newly Diagnosed High-Risk Neuroblastoma (Protocol Version Date 10/24/19)

IV. Continuing Review

ARST1431, A Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus (TORI, Torisel, NSC# 683864) in Patients with Intermediate Risk (IR) Rhabdomyosarcoma (RMS) (Protocol Version Date 11/16/20)

V. Continuing Review

PBTC-049, A Phase I study of Savolitinib in Recurrent, Progressive or Refractory Medulloblastoma, High-Grade Glioma, Diffuse Intrinsic Pontine Glioma and CNS tumors harboring MET aberrations. (Protocol Version Date 11/24/20)

VI. New Study - Initial Review

ANHL1931, A Randomized Phase 3 trial of Nivolumab (NSC# 748726 IND# 125462) in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma (Protocol Version Date 01/14/21)

VII. Unanticipated Problem and Serious Noncompliance Review Response

AALL0932, Treatment of Patients with Newly Diagnosed Standard Risk B-Lymphoblastic Leukemia (B-ALL) or Localized B-lineage Lymphoblastic Lymphoma (B-LLy) (Protocol Version Date 10/26/17)

VIII. Unanticipated Problem and Serious Noncompliance Review Response

AALL1131, A Phase III Randomized Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Including a Stratum Evaluating Dasatinib (IND#73789, NSC#732517) in Patients with Ph-like Tyrosine Kinase Inhibitor (TKI) Sensitive Mutations (Protocol Version Date 01/12/21)

IX. Unanticipated Problem and Serious Noncompliance Review Response

AAML1031, A Phase III Randomized Trial for Patients with de novo AML using Bortezomib and Sorafenib (IND#114480; NSC# 681239, NSC# 724772) for Patients with High Allelic Ratio FLT3/ITD (Protocol Version Date 04/24/17)
