

Pediatric CIRB Meeting Agenda

March 12, 2020

I. Continuing Review

AALL1231, A Phase III Randomized Trial Investigating Bortezomib (NSC# 681239; IND# 58443) on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T- Lymphoblastic Leukemia (T-ALL) and T- Lymphoblastic Lymphoma (T-LLy): A Groupwide Phase III Study (Protocol Version Date 05/29/19)

II. Continuing Review

AALL1331, Risk-Stratified Randomized Phase III Testing of Blinatumomab (IND# 117467, NSC#765986) in First Relapse of Childhood B-Lymphoblastic Leukemia (B-ALL): A Groupwide Phase III Study (Protocol Version Date 12/19/19)

III. Continuing Review

AALL1621, A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND#133494) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL) (Protocol Version Date 08/15/18)

IV. Continuing Review

AALL1731, A Phase 3 Trial Investigating Blinatumomab (IND# 117467, NSC# 765986) in Combination with Chemotherapy in Patients with Newly Diagnosed Standard Risk or Down syndrome B-Lymphoblastic Leukemia (B-ALL) and the Treatment of Patients with Localized B-Lymphoblastic Lymphoma (B-LLy) (Protocol Version Date 11/22/19)

V. Continuing Review

AAML1331, A Phase III Study for Patients with Newly Diagnosed Acute Promyelocytic Leukemia (APL) using Arsenic Trioxide and All-Trans Retinoic Acid: A COG Groupwide Phase III Study (Protocol Version Date 03/16/18)

VI. Continuing Review

ACNS1723, A Phase 2 Study of Dabrafenib (NSC# 763760) with Trametinib (NSC# 763093) after Local Irradiation in Newly-Diagnosed BRAFV600-Mutant High-Grade Glioma (HGG) (IND# 145355) (Protocol Version Date 12/06/19)

VII. Continuing Review

ADVL1622, Phase 2 Trial of XL184 (Cabozantinib), an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors (Protocol Version Date 04/16/19)

VIII. Continuing Review

AEWS1221, Randomized Phase 3 Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody Ganitumab (AMG 479, NSC# 750008, IND# 120449) to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma (Protocol Version Date 05/01/19)

IX. Continuing Review

AREN1721, A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Axitinib or Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups (Protocol Version Date 01/23/20)

X. New Study - Initial Review

AREN1921, Treatment of Newly Diagnosed Diffuse Anaplastic Wilms Tumors (DAWT) and Relapsed Favorable Histology Wilms Tumors (FHWT) (Protocol Version Date 03/02/20)

XI. Amendment

ANHL1522, A Pilot Study of Rituximab (RTX) and Third Party Latent Membrane Protein (LMP)-specific Cytotoxic T-Lymphocytes (LMP-TC, IND # 17068) in Pediatric Solid Organ Recipients (SOT) with EBV-Positive CD20-Positive Post-Transplant Lymphoproliferative Disease (PTLD) (Protocol Version Date 02/05/20)

XII. New Study - Initial 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 01/27/20)
