



## **Pediatric CIRB Meeting Agenda**

**November 11, 2021**

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### **I. 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)

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### **II. 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 09/17/21)

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### **III. 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 10/25/21)

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### **IV. Continuing Review**

**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 (Protocol Version Date 12/23/20)

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### **V. 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 06/21/21)

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**VI. Continuing Review**

**ADV1622**, 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)

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**VII. Continuing Review**

**AGCT1532**, Phase 3 Accelerated BEP Trial: A randomized phase 3 trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor-risk metastatic germ cell tumors (Protocol Version Date 04/22/21)

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**VIII. Continuing Review**

**APEC14B1**, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Protocol Version Date 08/26/20)

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**IX. Continuing Review**

**AREN1721**, A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups (Protocol Version Date 08/30/21)

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**X. New Study - Initial Review**

**ACNS1821**, A Phase 1/2 Trial of Selinexor (KPT-330, IND# TBD) and Radiation Therapy in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG) (Protocol Version Date 09/22/21)

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**XI. Amendment**

**AALL1821**, A Phase 2 Study of Blinatumomab (NSC# 765986, IND #147294) in Combination with Nivolumab (NSC# 748726, IND# 147294 Old ), a Checkpoint Inhibitor of PD-1, in B-ALL Patients Aged > 1 to < 31 Years Old with First Relapse (Protocol Version Date 10/07/21)

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**XII. Unanticipated Problem 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 10/25/21)

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**XIII. Unanticipated Problem Review**

**PEPN1924**, A Phase 2 Study of DS-8201A (NSC# 807708, IND# 153036) in Adolescents, or Young Adults with Recurrent HER2+ Osteosarcoma (Protocol Version Date 09/17/21)

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