

**Pediatric CIRB Meeting Agenda**

**July 13, 2023**

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**I. Amendment**

**ALTE05N1**, Umbrella Long-Term Follow-Up Protocol (Version Date 05/19/23)

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**II. Amendment Prior to Activation**

**AALL2121**, A Phase 2 study of SNDX-5613 in combination with chemotherapy for patients with relapsed or refractory KMT2A-rearranged infant leukemia (Version Date 06/07/23)

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**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) (Version Date 01/19/23)

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**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) (Version Date 09/14/22)

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**V. 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 (Version Date 04/06/23)

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**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) (Version Date 11/22/22)

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**VII. Continuing Review**

**ACNS1821**, A Phase 1/2 Trial of Selinexor (KPT-330) and Radiation Therapy in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG) (Version Date 11/07/22)

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**VIII. 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 (Version Date 04/16/19)

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**IX. 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 (Version Date 04/22/21)

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**X. Continuing Review**

**APEC14B1**, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Version Date 09/13/22)

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**XI. Continuing Review**

**PEPN2112**, A Phase 1/ 2 Study of BAY 1895344 (elimusertib, IND#152153, NSC#810486) in Pediatric Patients with Relapsed or Refractory Solid Tumors (Version Date 04/15/22)

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