

Pediatric CIRB Meeting Agenda

September 8, 2022

I. 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 07/15/22)

II. 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 04/12/22)

III. 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 04/26/22)

IV. 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 07/20/22)

V. Continuing Review

ACNS1821, A Phase 1/2 Trial of Selinexor (KPT-330, IND#159140) and Radiation Therapy in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG) (Protocol Version Date 07/29/22)

VI. 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)

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)

VIII. Continuing Review

APEC14B1, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Protocol Version Date 12/10/21)

IX. 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 (Protocol Version Date 04/15/22)

X. New Study - Initial Review

ASCT2031, A Multi-Center, Phase 3, Randomized Trial of Matched Unrelated Donor (MUD) versus HLA-Haploidentical Related (Haplo) Myeloablative Hematopoietic Cell Transplantation for Children, Adolescents, and Young Adults (AYA) with Acute Leukemia or Myelodysplastic Syndrome (MDS) (Protocol Version Date 07/27/22)
