

Pediatric CIRB Meeting Agenda

June 13, 2024

I. Initial Review

ACNS2321, A Phase II Trial Evaluating Chemotherapy followed by Response-Based Reduced Radiation Therapy for Patients with Central Nervous System Germinomas (Version Date 03/15/24)

II. Amendment

PED-CITN-02, GD2-CAR PERSIST: Production and Engineering of GD2-Targeted, Receptor Modified T Cells (GD2CART) for Osteosarcoma or Neuroblastoma to Increase Systemic Tumor Exposure (Version Date 04/19/24)

III. Continuing Review

AALL1732, A Phase 3 Randomized Trial of Inotuzumab Ozogamicin (IND#:133494, NSC#: 772518) for Newly Diagnosed High-Risk B-ALL; Risk-Adapted Post-Induction Therapy for High-Risk B-ALL, Mixed Phenotype Acute Leukemia, and Disseminated B-LLy (Version Date 10/12/23)

IV. Continuing Review

ACCL1931, A Randomized Trial of Levocarnitine Prophylaxis to Prevent Asparaginase-Associated Hepatotoxicity in Adolescents and Young Adults Receiving Acute Lymphoblastic Leukemia Therapy (Version Date 12/21/22)

V. Continuing Review

AREN1921, Treatment of Newly Diagnosed Diffuse Anaplastic Wilms Tumors (DAWT) and Relapsed Favorable Histology Wilms Tumors (FHWT) (Version Date 05/17/22)

VI. Continuing 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) (Version Date 12/19/23)

VII. Unanticipated Problem Review

ALTE1631, A Randomized Web-based Physical Activity Intervention among Children and Adolescents with Cancer (Version Date)
