

Pediatric CIRB Meeting Agenda

August 10, 2023

I. Amendment Prior to Activation

ACCL1932, Letermovir Prophylaxis for Cytomegalovirus in Pediatric Hematopoietic Cell Transplantation (Version Date 07/11/23)

II. 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 10/12/22)

III. Continuing Review

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

IV. 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 09/26/22)

V. Continuing Review

PBTC-051, Phase I Study to Evaluate the Safety and Tolerability of the CD40 Agonistic Monoclonal Antibody APX005M in Pediatric Subjects with Recurrent/Refractory Brain Tumors and Newly Diagnosed Brain Stem Glioma (Version Date 09/23/22)

VI. 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 07/24/23)
