

Pediatric CIRB Meeting Agenda

June 12, 2025

I. Initial Review

ACCL2531, A Randomized Double-Blinded Trial of Xylitol Dental Wipes for the Prophylaxis of Bloodstream Infections from Oral Organisms in Pediatric Patients with Acute Myeloid Leukemia (Version Date 05/02/25)

II. Initial Review

PEPN2413, A Phase 1 study of oral cedazuridine and decitabine combination (ASTX727, IND# TBD, NSC# 820631) and filgrastim as maintenance therapy post-hematopoietic stem cell transplant in children with high-risk acute myeloid leukemia (Version Date 04/22/25)

III. Amendment

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 04/15/25)

IV. Amendment

ANBL2131, A Phase 3 Study of Dinutuximab Added to Intensive Multimodal Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (Version Date 05/07/25)

V. Continuing Review

ACNS2021, A Phase 2 Trial of Chemotherapy followed by Response-Based Whole Ventricular & Spinal Canal Irradiation (WVSCI) for Patients with Localized Non-Germinomatous Central Nervous System Germ Cell Tumor (Version Date 03/29/24)

VI. Continuing Review

AGCT1531, A Phase 3 Study of Active Surveillance for Low risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors (Version Date 05/19/25)

VII. Continuing Review

ANHL1931, A Randomized Phase 3 trial of Nivolumab(NSC# 748726 IND# 125462) in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma (Version Date 01/30/24)

VIII. Continuing Review

AOST2031, A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma (Version Date 01/04/24)

IX. Unanticipated Problem Review

ALTE05N1, Umbrella Long-Term Follow-Up Protocol (Version Date 05/29/24)
