

Pediatric CIRB Meeting Agenda

July 11, 2024

I. Initial Review

ALTE2131, Triptorelin and Protection of Ovarian Reserve in Adolescents and Young Adults with Cancer (Version Date 06/10/24)

II. Amendment

ANBL1531, A Phase 3 Study of ¹³¹I-Metaiodobenzylguanidine (¹³¹I-MIBG) or ALK Inhibitor Therapy Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL) (IND# 134379) (Version Date 06/18/24)

III. Amendment

PEPN22P1, A Pharmacokinetic Study of VinCRISTine in Infants Dosed According to BSA-Banded Infant Dosing Tables and Older Children Dosed by Traditional BSA Methods (Version Date 06/04/24)

IV. Continuing Review

AOST2032, A Feasibility and Randomized Phase 2/3 Study of the VEGFR2/MET Inhibitor Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma (Version Date 09/26/23)

V. Continuing Review

APAL2020SC, Pediatric Acute Leukemia (PedAL) Screening Trial – Developing New Therapies for Relapsed Leukemias (Version Date 04/22/24)

VI. Continuing Review

PBTC-049, A Phase I study of Savolitinib in Recurrent, Progressive or Refractory Medulloblastoma, High-Grade Glioma, Diffuse Intrinsic Pontine Glioma and CNS tumors harboring MET aberrations. (Version Date 08/31/23)

VII. Continuing Review

PBTC-058, Phase 2 Study of Intraventricular Omburtamab-based Radioimmunotherapy for Pediatric Patients with Recurrent Medulloblastoma and Ependymoma (Version Date 06/10/22)
