

Pediatric CIRB Meeting Agenda

September 14, 2023

I. Initial Review

PBTC-061, Phase 2 Trial of G207 + 5 Gy Radiation for Children with High-Grade Gliomas (Version Date 08/22/23)

II. Amendment

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) (Version Date 07/27/23)

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 08/07/23)

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 12/20/22)

V. Continuing Review

APAL2020SC, Pediatric Acute Leukemia (PedAL) Screening Trial – Developing New Therapies for Relapsed Leukemias (Version Date 07/18/23)

VI. Continuing Review

ARST1431, A Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus (TORI, Torisel, NSC# 683864) in Patients with Intermediate Risk (IR) Rhabdomyosarcoma (RMS) (Version Date 11/16/20)

VII. 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 10/06/22)

VIII. 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)

IX. Continuing Review

PED-CITN-03, Phase 1 Trial of Hu5F9-G4 (Magrolimab) Combined with Dinutuximab in Children and Young Adults with Relapsed and Refractory Neuroblastoma or Relapsed Osteosarcoma (Version Date 04/28/23)
