



## **Pediatric CIRB Meeting Agenda**

**February 10, 2022**

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### **I. 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 (Protocol Version Date 11/17/21)

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### **II. 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 (Protocol Version Date 09/30/21)

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### **III. Continuing Review**

**ANBL19P1**, A Pilot Study of Dinutuximab, Sargramostim (GM-CSF), and Isotretinoin in Combination with Irinotecan and Temozolomide in the Post-Consolidation Setting for High-Risk Neuroblastoma (Protocol Version Date 07/15/20)

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### **IV. 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 (Protocol Version Date 07/19/21)

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### **V. Amendment**

**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 (Protocol Version Date 01/05/22)

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**VI. Unanticipated Problem and Serious and/or Continuing Noncompliance Review**

**PBTC-056**, A Phase I Study of the ADAM-10 inhibitor, INCB007839 in Children with Recurrent/Progressive High-Grade Gliomas to Target Microenvironmental Neuroligin-3 (Protocol Version Date 05/27/21)

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