

**Pediatric CIRB Meeting Agenda**

**November 10, 2022**

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**I. New Study - Initial 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 09/19/22)

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**II. Patient Recruitment Material/Info Docs ReReview**

**APEC14B1**, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Version Date 09/13/22)

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**III. Continuing Review**

**APAL2020SC**, Pediatric Acute Leukemia (PedAL) Screening Trial – Developing New Therapies for Relapsed Leukemias (Version Date 10/28/21)

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**IV. 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)

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**V. 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 05/12/21)

## **VI. 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)

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## **VII. 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 07/26/22)

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## **VIII. Potential Unanticipated Problem and Serious and/or Continuing Noncompliance Review**

**ACCL2031**, A Phase 3 Randomized, Placebo-Controlled Trial Evaluating Memantine (IND #149832) for Neurocognitive Protection in Children Undergoing Cranial Radiotherapy as Part of Treatment for Primary Central Nervous System Tumors (Version Date 06/07/21)

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## **IX. Potential Unanticipated Problem and Serious and/or Continuing Noncompliance Review**

**Multi-Study**, This event relates to the following studies: AALL15P1, AALL1331, AALL1731, AAML1031, AAML1831, ACCL1033, ACNS0831, ACNS1022, ACNS1123, ACNS1723, ALTE07C1, ALTE1631, ANBL00B1, ANBL1232, ANHL12P1, AREN1921, ARST1431 (Version Date 09/25/19)

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