

**Pediatric CIRB Meeting Agenda**

**October 13, 2022**

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**I. Amendment**

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

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**II. New Study - Initial Review**

**ACCL1931**, A Randomized Trial of Levocarnitine Prophylaxis to Prevent Asparaginase-Associated Hepatotoxicity in Adolescents and Young Adults Receiving Acute Lymphoblastic Leukemia Therapy (Version Date 08/29/22)

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**III. Amendment**

**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 08/10/22)

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**IV. Amendment**

**ARST1921**, A Safety, Pharmacokinetic and Efficacy Study of a  $\gamma$ -Secretase Inhibitor, Nirogacestat (PF 03084014; IND# 146375), in Children and Adolescents with Progressive, Surgically Unresectable Desmoid Tumors (Version Date 08/22/22)

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**V. Amendment**

**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 (Version Date 08/08/22)

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**VI. Continuing Review**

**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 09/13/21)

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**VII. Continuing Review**

**AREN1721**, A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups (Version Date 12/14/21)

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**VIII. Continuing Review**

**AREN1921**, Treatment of Newly Diagnosed Diffuse Anaplastic Wilms Tumors (DAWT) and Relapsed Favorable Histology Wilms Tumors (FHWT) (Version Date 05/17/22)

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**IX. Continuing Review**

**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 (Version Date 02/23/22)

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

**APEC14B1**, The Project:Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Version Date 12/10/21)

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**XI. Potential Unanticipated Problem and Serious and/or Continuing Noncompliance 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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