

**Pediatric CIRB Meeting Agenda**

**January 16, 2025**

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**I. Continuing Review**

**ACNS1831**, A Phase 3 Randomized Study of Selumetinib (IND # 77782) versus Carboplatin/Vincristine in Newly Diagnosed or Previously Untreated Neurofibromatosis Type 1 (NF1) Associated Low-Grade Glioma (LGG) (Version Date 09/16/22)

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**II. Continuing Review**

**ACNS2031**, A Phase 3 Study of Sodium Thiosulfate for Reduction of Cisplatin-Induced Ototoxicity in Children with Average-Risk Medulloblastoma and Reduced Therapy in Children with Medulloblastoma with Low-Risk Features (Version Date 10/28/22)

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**III. Continuing Review**

**ANBL1232**, Utilizing Response- and Biology-Based Risk Factors to Guide Therapy in Patients with Non-High-Risk Neuroblastoma. A Groupwide Historically Controlled Phase III Study (Version Date 11/17/22)

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**IV. Continuing Review**

**ANBL1531**, A Phase 3 Study of <sup>131</sup>I-Metaiodobenzylguanidine (<sup>131</sup>I-MIBG) or ALK Inhibitor Therapy Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL) (IND# 134379) (Version Date 08/26/24)

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## **V. Continuing Review**

**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 10/18/23)

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