

Pediatric CIRB Meeting Agenda

September 10, 2026

I. Initial Review

PEPN2611, A Phase 1/2 Study of Daraxonrasib (RMC-6236) (NSC# 858328, IND# TBD) in Patients with Relapsed or Refractory RAS-driven Tumors (Version Date 07/31/26)

II. 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 05/15/25)

III. 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 03/05/25)

IV. Continuing Review

ANBL1531, A Phase 3 Study of ¹³¹I-Metaiodobenzylguanidine (¹³¹I-MIBG) or ALK Inhibitor Therapy Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL) (IND# 134379) (Version Date 06/09/26)

V. Continuing Review

ARST1921, A Safety, Pharmacokinetic and Efficacy Study of a γ -Secretase Inhibitor, Nirogacestat (PF 03084014; IND# 146375), in Children and Adolescents with Progressive, Surgically Unresectable Desmoid Tumors (Version Date 05/19/26)
