

Pediatric CIRB Meeting Agenda

March 14, 2024

I. Amendment

ACNS1821, A Phase 1/2 Trial of Selinexor (KPT-330) and Radiation Therapy in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG) (Version Date 01/17/24)

II. Amendment

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 (Version Date 02/02/24)

III. 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)

IV. 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)

V. 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)

VI. 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 03/14/23)

VII. 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 10/18/23)
