

Pediatric CIRB Meeting Agenda

December 14, 2023

I. Amendment

AAML1831, A Phase 3 Randomized Trial for Patients with De Novo AML Comparing Standard Therapy Including Gemtuzumab Ozogamicin (GO) to CPX-351 with GO, and the Addition of the FLT3 Inhibitor Gilteritinib for Patients with FLT3 Mutations (Version Date 09/22/23)

II. Amendment

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)

III. Continuing Review

ACNS1422, A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients (Version Date 02/02/23)

IV. Continuing Review

ARST2032, A Prospective Phase 3 Study of Patients with Newly Diagnosed Very Low-risk and Low-risk Fusion Negative Rhabdomyosarcoma (Version Date 12/05/22)

V. Continuing Review

PBTC-055, Phase I/II trial of Dabrafenib, Trametinib, and Hydroxychloroquine (HCQ) for BRAF V600E-mutant or Trametinib and HCQ for BRAF fusion/duplication positive or NF1-associated recurrent or progressive gliomas in children and young adults (Version Date 09/20/22)

VI. Continuing Review

PEPN2111, A Phase 1/2 Trial of CBL0137 (NSC# 825802, IND# 155843) in Patients with Relapsed or Refractory Solid Tumors including CNS Tumors and Lymphoma (Version Date 05/01/23)

VII. Unanticipated Problem 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)
