

Public Agenda Pediatric Meeting

February 9, 2023

I New Study - Initial Review

AALL2121, A Phase 2 study of SNDX-5613 in combination with chemotherapy for patients with relapsed or refractory KMT2A-rearranged infant leukemia (Version Date 12/27/22)

II Amendment 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 12/16/22)

III Continuing Review

AALL08B1, Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL) (Version Date 03/13/18)

IV Continuing Review

ACNS1422, A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients (Version Date 10/07/19)

V 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)

VI 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)

VII Continuing Review

PEPN2111, A Phase 1/2 Trial of CBL0137 (NSC# 825802, IND# TBD) in Patients with Relapsed or Refractory Solid Tumors including CNS Tumors and Lymphoma (Version Date 07/07/21)

VIII Potential Unanticipated Problem and Serious and/or Continuing Noncompliance Review

AALL08B1, Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL) (Version Date 03/13/18)
