

Adult CIRB - Early Phase Emphasis Meeting Agenda

March 17, 2026

I New Study - Initial Review

EAA242, Phase Ib/II Fixed Duration Study of Teclistamab/Pomalidomide (TP) versus Carfilzomib/Pomalidomide/Dexamethasone (KPd) in Early Relapse of Multiple Myeloma (Version Date 01/30/26)

II Amendment

10601, A Phase 1 Study of Mosunetuzumab with Polatuzumab Vedotin and Lenalidomide (M+Pola+Len) in Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL) (Version Date 02/13/26)

III Amendment

10596, A Phase Ib Study of Menin Inhibitor SNDX-5613 in Combination with Daunorubicin and Cytarabine in Newly Diagnosed Patients with Acute Myeloid Leukemia and NPM1 Mutated/FLT3 Wildtype or MLL/KMT2A Rearranged or NUP98 Alterations Disease (Version Date 02/03/26)

IV Continuing Review

10695, Phase 1 Study of Lintuzumab-Ac225 Monotherapy for Patients with Hypomethylating Agent-Refractory Myelodysplastic Syndrome (Version Date 05/07/25)

V Continuing Review

10614, A Phase 2 Study of Nivolumab and Ipilimumab in Combination with Sirolimus and Prednisone in Kidney Transplant Recipients with Selected Unresectable or Metastatic Cutaneous Cancers (Version Date 08/01/25)
