

Adult CIRB - Early Phase Emphasis Meeting Agenda

August 5, 2025

I New Study - Initial Review

10708, A Phase 2 Pilot Study of Mirdametinib in Relapsed Refractory Chronic Lymphocytic Leukemia (Version Date 06/17/25)

II New Study - Initial Review

10717, Phase 1b/2 Trial of Pidnarulex in MYC Aberrant Lymphoma (Version Date 06/16/25)

III Continuing Review

EAY191-A3, A ComboMATCH Treatment Trial: Palbociclib and Binimetinib in RAS-Mutant Cancers (Version Date 09/04/24)

IV Continuing Review

EAY191-E4, A ComboMATCH Treatment Trial ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients with Prior Taxane-Treated Solid Tumors (Version Date 12/20/23)

V Continuing Review

10358, Phase 1/1B study of DS-8201a in combination with ATR Inhibition (AZD6738) in advanced solid tumors with HER2 expression (DASH Trial) (Version Date 04/15/25)

VI Continuing Review

10299, A Phase I Study to Investigate the Safety of the Ubiquitin Activating Enzyme Inhibitor TAK-243 in Adult Solid Tumor and Lymphoma Patients (Version Date 02/21/25)

VII Continuing Review

10327, A Phase 1 Trial of MLN0128 (sapanisertib) and Telaglenastat (CB-839) HCl in Advanced NSCLC Patients (Version Date 01/10/25)

VIII Continuing Review

10440, A Phase 1/1a Study of Venetoclax, MLN9708 (ixazomib citrate) and Dexamethasone for Relapsed/Refractory Light Chain Amyloidosis (Version Date 01/02/25)

IX Continuing Review

10612, A Randomized Phase 2 Study of Daratumumab-Selinexor-Velcade-Dexamethasone (Dara-SVD) for High-Risk Newly Diagnosed Multiple Myeloma (Version Date 05/13/25)

X Continuing Review ReReview

10559, A Phase 2 Study of Erdafitinib in Patients with Recurrent or Progressive IDH-Wild Type Glioma with an FGFR-TACC Gene Fusion (Version Date 06/04/25)
