

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 15, 2025

I New Study ReReview

10666, A First-in-Human Dose-Finding Phase I Study of Bone-targeted High Specific Activity Stannic-117m Pentatate (Sn-117m-DTPA) in Solid Tumors with Skeletal Metastases (Version Date 06/18/25)

II Continuing Review

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 02/04/25)

III Amendment

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)

IV Amendment

10509, A Phase 1 Study of BET Bromodomain Inhibitor ZEN003694 in Combination with the CDK4/6 Inhibitor Abemaciclib in Patients with NUT Carcinoma, Breast Cancer and Other Solid Tumors (Version Date 06/13/25)

V Continuing Review

10596, A Phase 1b 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 with Higher-Risk Features or MLL/KMT2A Rearranged Disease (Version Date 03/19/25)

VI Continuing Review

EAY191-S3, EAY191-S3, Phase II Study of Paclitaxel (NSC #673089) + Ipatasertib (NSC #781451) in Taxane-Refractory Participants with PTEN/AKT-Altered Advanced Non-Breast Solid Tumors (A COMBOMATCH Treatment Trial) (Version Date 01/15/25)

VII Continuing Review

EAY191-A6, A ComboMATCH Treatment Trial: FOLFOX in Combination with Binimetinib as 2nd Line Therapy for Patients with Advanced Biliary Tract Cancers with MAPK Pathway Alterations (Version Date 08/14/24)

VIII Continuing Review

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 05/13/25)
