

Adult CIRB - Early Phase Emphasis Meeting Agenda

August 20, 2024

I New Study - Initial Review

10636, Phase 1 Trial of CA-4948 in Combination with Pembrolizumab to Overcome Resistance to PD-1/PD-L1 Blockade in Metastatic Urothelial Cancer (Version Date 07/16/24)

II Amendment

10276, A Phase I/II Study of PEPOSERTIB and Avelumab in Combination with Hypofractionated Radiation in Patients with Advanced/Metastatic Solid Tumors and Hepatobiliary Malignancies (Version Date 07/19/24)

III 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 05/14/24)

IV 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 01/17/24)

V 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 12/05/23)

VI 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 02/28/24)

VII 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 11/02/23)
