



Adult CIRB - Early Phase Emphasis Meeting Agenda

June 2, 2026

I Amendment

10495, Phase I Trial of DS-8201a (Trastuzumab Deruxtecan) in Combination with Neratinib in Solid Tumors with HER2 Alterations (Version Date 05/01/26)

II New Study - Initial Review

10733, Phase I/II study of the MEK inhibitor Selumetinib plus DS-8201a in KRAS-mutant, HER2-expressing pancreatic ductal adenocarcinoma (Version Date 04/21/26)

III Amendment

10449, A Phase 1 Study of ZEN003694 in Combination with Binimetinib in Solid Tumors with RAS Pathway Alterations and Triple Negative Breast Cancer (Version Date 04/16/26)

IV Amendment

10487, A Phase II study of Lutetium Lu 177 dotatate in metastatic prostate cancer with neuroendocrine differentiation (Version Date 04/24/26)

V Continuing Review

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 04/02/26)

VI 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 02/13/26)

VII 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)
