

Adult CIRB - Early Phase Emphasis Meeting Agenda

May 7, 2024

I New Study - Initial Review

10554, Phase 1 Study of Trastuzumab Deruxtecan (DS-8201a) in Combination with Azenosertib (ZN-c3) in HER2-Expressing/Amplified Cyclin E-Amplified Gastric/Gastroesophageal Junction Cancer and Other Solid Tumors with HER2 Expression (Version Date 03/19/24)

II New Study ReReview

10640, Phase 2 and Biomarker Trial of anti-TIGIT and anti-PDL1 in Patients with Recurrent Glioblastoma (Version Date 04/05/24)

III Continuing Review

10276, A Phase I/II Study of M3814 and Avelumab in Combination with Hypofractionated Radiation in Patients with Advanced/Metastatic Solid Tumors and Hepatobiliary Malignancies (Version Date 09/22/23)

IV Continuing Review

10487, A Phase II study of Lutetium Lu 177 dotatate in metastatic prostate cancer with neuroendocrine differentiation (Version Date 01/29/24)

V Continuing Review

10579, Phase I trial of ZEN003694 (ZEN-3694) in combination with capecitabine in patients with solid tumors (Version Date 12/22/23)

VI Continuing Review

10603, A Phase 2 Study of M1774 in Refractory SPOP-mutant Prostate Cancer (Version Date 01/19/24)

VII Continuing Review

10324, A Phase I/Ib Dose Escalation Study of Pegylated Liposomal Doxorubicin (PLD) With Peposertib (M3814) in Platinum-Resistant or Ineligible Ovarian and Related Cancers with Planned Expansions in High Grade Serous (HGSOC) and Low Grade Serous Ovarian Cancer (LGSOC) (Version Date 01/18/24)

VIII Continuing Review

10433, Phase I/Ib trial evaluating the safety and efficacy of BET inhibitor, ZEN003694 with PD-1 inhibitor, nivolumab with or without CTLA-4 inhibitor, ipilimumab in solid tumors (Version Date 09/21/23)

IX Continuing Review

10556, Randomized Phase 2 Study of Cabozantinib, Ipilimumab, and Nivolumab in Patients with Soft Tissue Sarcoma (Version Date 10/06/23)
