



Adult CIRB - Early Phase Emphasis Meeting Agenda

February 17, 2026

I Amendment

10554, Phase 1 Study of Trastuzumab Deruxtecan (DS-8201a) in Combination with Azenosertib (ZN-c3) in HER2-Expressing/Amplified Gastric/Gastroesophageal Junction Cancer and Other Solid Tumors (Version Date 11/03/25)

II Continuing Review

10487, A Phase II study of Lutetium Lu 177 dotatate in metastatic prostate cancer with neuroendocrine differentiation (Version Date 02/26/25)

III Continuing Review

10301, A Phase I and Randomized Phase II Trial of Radium-223 dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC) (Version Date 11/21/25)

IV 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 11/06/25)

V Continuing Review

10276, A Phase I/II Study of Peposertib (M3814) and Avelumab in Combination with Hypofractionated Radiation in Patients with Advanced/Metastatic Solid Tumors and Hepatobiliary Malignancies (Version Date 10/15/25)



VI Continuing Review

10579, Phase I trial of ZEN003694 (ZEN-3694) in combination with capecitabine in patients with solid tumors (Version Date 10/24/25)

VII Continuing Review

10703, A Phase I/II Trial of Sapanisertib in Combination with Cabozantinib in β -catenin-mutated Hepatocellular Carcinoma (SAPHIRE) (Version Date 12/16/25)

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 11/04/25)

IX Continuing Review

10556, Randomized Phase 2 Study of Cabozantinib, Ipilimumab, and Nivolumab in Patients with Soft Tissue Sarcoma (Version Date 09/08/25)
