

Adult CIRB - Early Phase Emphasis Meeting Agenda

November 7, 2023

I New Study - Initial Review

10605, A Phase 1 Study of ZEN003694 (ZEN-3694) in Combination with Cetuximab and Encorafenib in Patients with Refractory BRAF V600E Metastatic Colorectal Cancer (Version Date 09/05/2023)

II Continuing Review

10144, A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma and other genitourinary tumors with DNA-Repair Defects (Version Date 07/10/23)

III Continuing Review

10183, A Pilot Study of Tazemetostat and Pembrolizumab (MK-3475) in Advanced Urothelial Carcinoma (Version Date 02/14/23)

IV Continuing Review

10538, Venetoclax In Combination with ASTX727, an All-ORal TherapY for Chronic Myelomonocytic Leukemia and Other MDS/MPN with Excess Blasts (VICTORY-MDS/MPN): a Randomized, Phase 2 trial (Version Date 06/02/23)

V Continuing Review

10480, Phase Ib/II Study of EPA-based EphA2 Targeted Therapy for Patients with Metastatic Triple-Negative Inflammatory Breast Cancer (Version Date 12/13/22)
