

Adult CIRB - Early Phase Emphasis Meeting Agenda

February 7, 2023

I New Study - Initial Review

10577, Pilot Study of CBX-12 Pharmacodynamics in Patients with Advanced Solid Tumors (Version Date 11/22/22)

II New Study - Initial Review

10597, A Phase 1 Study of APG-1252 (pelcitoclax) and cobimetinib in recurrent ovarian and endometrial cancers (Version Date 12/16/22)

III New Study ReReview

10527, A Molecularly Driven Phase 1b Dose Escalation and Dose Expansion Study of the DNA-PK Inhibitor Peposertib (M3814) in Combination with the ATR Inhibitor M1774 (Version Date 01/06/23)

IV Continuing Review

10264, The PRIME Trial: PARP Inhibition in IDH Mutant Effectiveness Trial. A Phase II Study of Olaparib in Isocitrate Dehydrogenase (IDH) Mutant Relapsed/Refractory Acute Myeloid Leukemia and Myelodysplastic Syndrome (Version Date 11/16/22)

V Continuing Review

10504, A Randomized Phase 2 Study of Atezolizumab with or without Selinexor in Alveolar Soft Part Sarcoma (AXIOM) (Version Date 01/06/23)

VI Continuing Review

10434, Randomized Phase 2 Study of daunorubicin and cytarabine liposome + Pomalidomide versus daunorubicin and cytarabine liposome in Newly Diagnosed AML with MDS-Related Changes (Version Date 11/07/22)
