

Adult CIRB - Early Phase Emphasis Meeting Agenda

January 2, 2024

I Amendment

10528, A Phase 1 Study of the Polymerase Theta (POL θ) Inhibitor Novobiocin in BRCA-mutant and Other DNA Damage Repair-Deficient Solid Tumors (Version Date 11/06/23)

II 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 07/11/23)

III Continuing Review

10504, A Randomized Phase 2 Study of Atezolizumab with or without Selinexor in Alveolar Soft Part Sarcoma (AXIOM) (Version Date 09/29/23)

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 07/27/23)

V Continuing Review

10527, A Molecularly Driven Phase 1b Dose Escalation and Dose Expansion Study of the DNA-PK Inhibitor Pepsertib (M3814) in Combination with the ATR Inhibitor M1774 (Version Date 06/30/23)

VI Continuing Review

10273, A Phase 1 Study of M3814 in combination with MEC in Patients with Relapsed or Refractory Acute Myeloid Leukemia (Version Date 11/01/21)
