

Adult CIRB - Early Phase Emphasis Meeting Agenda

November 4, 2025

I Continuing Review

10504, A Phase 2 Study of Atezolizumab with Selinexor in Alveolar Soft Part Sarcoma (AXIOM) (Version Date 03/17/25)

II Continuing Review

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 Tuvusertib (M1774) (Version Date 05/02/25)

III Continuing Review

10597, A Phase 1 Study of APG-1252 (pelcitoclax) and cobimetinib in recurrent ovarian and endometrial cancers (Version Date 05/12/25)

IV Continuing Review

10675, A Randomized Phase 2 Trial of ASTX727 +/- Iadademstat in Accelerated/Blast-Phase Philadelphia Chromosome-Negative Myeloproliferative Neoplasms (MPNs) (Version Date 04/24/25)

V Continuing Review

10273, A Phase 1 Study of M3814 in combination with MEC in Patients with Relapsed or Refractory Acute Myeloid Leukemia (Version Date 01/15/25)