

Adult CIRB - Early Phase Emphasis Meeting Agenda

February 4, 2025

I New Study - Initial Review

10653, A Phase I Study of Lintuzumab-Ac225 in Combination with Venetoclax and ASTX-727 in Adults with Newly Diagnosed AML (Version Date 12/18/24)

II Amendment

10355, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Version Date 11/18/24)

III Continuing Review

10486, Phase 2 Trial of the Combination of the BET inhibitor, ZEN003694 (ZEN-3694), and the PARP Inhibitor Talazoparib, in Patients with Molecularly-Selected Solid Tumors (ComBET) (Version Date 10/28/24)

IV Continuing Review

9681, A Phase 1 Study of Cabozantinib plus Nivolumab (CaboNivo) Alone or in Combination with Ipilimumab (CaboNivoIpi) in Patients with Advanced/Metastatic Urothelial Carcinoma and other Genitourinary Tumors. (Version Date 12/18/24)

V Continuing Review

AMC-110, Risk-Adapted Therapy for HIV-Associated Anal Cancer (Version Date 08/15/24)
