

Adult CIRB - Early Phase Emphasis Meeting Agenda

April 4, 2023

I New Study - Initial Review

10551, A Phase 1/1b Study of Anti-CD47 Hu5F9-G4 (Magrolimab) in Combination with Olaparib in Patients with BRCA1/2-mutant Tumors (Version Date 02/27/23)

II Amendment Prior to Activation

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 03/08/23)

III Amendment

10433, Phase I/Ib trial evaluating the safety and efficacy of BET inhibitor, ZEN003694 with PD-1 inhibitor, nivolumab with or without CTLA-4 inhibitor, ipilimumab in solid tumors (Version Date 03/02/23)

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 01/04/23)