

Adult CIRB - Early Phase Emphasis Meeting Agenda

May 3, 2022

I Continuing Review

10211, A Phase 2 Single-Arm Study of M6620 in Combination with Irinotecan in Patients with Progressive TP53 Mutant Gastric and Gastro-Esophageal Junction Cancer (Protocol Version Date 12/20/21)

II 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. (Protocol Version Date 06/21/21)

III New Study - Initial 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) (Protocol Version Date 03/24/22)

IV Amendment

10402, BAY 1895344 Plus Topoisomerase-1 (Top1) Inhibitors in Patients with Advanced Solid Tumors, Phase I Studies with Expansion Cohorts in Small Cell Lung Carcinoma (SCLC), Poorly Differentiated Neuroendocrine Carcinoma (PD-NEC) and Pancreatic Adenocarcinoma (PDA) (Protocol Version Date 03/21/22)
