

Adult CIRB - Early Phase Emphasis Meeting Agenda

June 15, 2021

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 02/15/21)

II Continuing Review

10398, A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Chondrosarcoma and Clear Cell Sarcoma (Protocol Version Date 05/17/21)

III 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 01/15/21)

IV Amendment

10313, A phase IB and randomized open-label phase II study of M6620 (VX-970, berzosertib) in combination with carboplatin/gemcitabine/ pembrolizumab in patients with chemotherapy-naïve advanced non-small cell lung cancer of squamous cell histology (Protocol Version Date 05/14/21)
