

Adult CIRB - Early Phase Emphasis Meeting Agenda

November 5, 2024

I New Study - Initial Review

10670, A Phase 1 Study of 5-Fluorouracil in Combination with Abemaciclib in Metastatic, Refractory CRC (Version Date 09/23/24)

II Continuing Review

10096, A Phase 1/2 Study of Combination Olaparib and Radium-223 in Men with Metastatic Castration-Resistant Prostate Cancer with Bone Metastases (COMRADE) (Version Date 07/24/23)

III Continuing Review

10222, A Phase II study of olaparib and AZD6738 in isocitrate dehydrogenase (IDH) mutant solid tumors (Version Date 08/15/24)

IV Continuing Review

10292, DURVA+: Evaluation of the Safety and Pharmacodynamics of Anti-PD-L1 Antibody Durvalumab in Combination with Chemotherapy in Patients with Advanced Solid Tumors (Version Date 06/05/24)

V Continuing Review

10313, A phase IB and randomized open-label phase II study of Berzosertib (M6620, VX-970) in combination with carboplatin/gemcitabine/pembrolizumab in patients with chemotherapy-naïve advanced non-small cell lung cancer of squamous cell histology (Version Date 02/23/23)

VI Continuing Review

9898, A Phase I Trial of Osimertinib (AZD9291) and Necitumumab in EGFR-Mutant Non-Small Cell Lung Cancer After Progression on a Previous EGFR Tyrosine Kinase Inhibitor (Version Date 08/20/24)
