

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 5, 2023

I 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)

II Continuing Review

10222, A Phase II study of olaparib and AZD6738 in isocitrate dehydrogenase (IDH) mutant solid tumors (Version Date 07/19/23)

III 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 08/01/23)

IV 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)

V Continuing Review

10330, A Phase 2 Study of Belinostat and SGI-110 (Guadecitabine) or ASTX727 for the Treatment of Unresectable and Metastatic Conventional Chondrosarcoma (Version Date 02/14/23)

VI Continuing Review

10334, BLockade of PD-1 Added to Standard Therapy to target Measurable Residual Disease in Acute Myeloid Leukemia 2 (BLAST MRD AML-2): A randomized Phase 2 Study of the Venetoclax, Azacitidine, and Pembrolizumab (VAP) Versus Venetoclax and Azacitidine as First Line Therapy in Older Patients with Acute Myeloid Leukemia (AML) who are Ineligible or who Refuse Intensive Chemotherapy (Version Date 02/10/23)

VII Continuing Review

10445, Phase I Dose Escalation and Expansion Study of Tazemetostat in Combination with Topotecan and Pembrolizumab in Recurrent Small Cell Lung Cancer (Version Date 02/10/23)

VIII Continuing Review

10572, A Phase 1/2 Trial Evaluating the Combination of Temozolomide and the Ataxia Telangiectasia and Rad3-related Inhibitor M1774 (Version Date 05/02/23)

IX Continuing Review

CITN-17, Phase 1 Study of NT-I7 (rhIL-7-hyFc) for the Treatment of Kaposi Sarcoma in Patients With or Without Infection with HIV (Version Date 11/29/22)

X Continuing Review

10150, A randomized phase 2 study of bevacizumab and either weekly anetumab ravtansine or weekly paclitaxel in platinum-resistant or platinum refractory ovarian cancer (Version Date 07/28/21)

XI Continuing Review

10450, A Phase 1b Trial of M3814 (Peposertib) in Combination with Lutetium 177 Dotatate for Well-Differentiated Somatostatin Receptor-Positive

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Version Date 06/28/23)

Continuing Review

10522, A Phase 1 Clinical Trial of CA-4948 in Combination with Gemcitabine and Nab-Paclitaxel in Metastatic or Unresectable Pancreatic Ductal Carcinoma (Version Date 06/15/23)

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 06/26/23)
