

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 1, 2020

I Continuing Review

10009, A Phase 1b study of the anti-PD1 antibody Pembrolizumab in combination with the histone deacetylase inhibitor, Entinostat for treatment of patients with myelodysplastic syndromes after DNA methyltransferase inhibitor therapy failure (Protocol Version Date 09/04/20)

II Continuing Review

10042, A Phase II trial of AZD9291 (osimertinib) with or without bevacizumab in patients with EGFR mutation positive NSCLC and brain metastases (Protocol Version Date 06/11/20)

III Continuing Review

10221, A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in patients with advanced solid tumors (Protocol Version Date 07/15/20)

IV Continuing Review

10246, A Phase 1 Study of MLN4924 (pevonedistat) and Belinostat in Relapsed/Refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome (Protocol Version Date 08/18/20)

V Continuing Review

10313, A phase IB and randomized open-label phase II study of M6620 in combination with carboplatin/gemcitabine/avelumab in patients with chemotherapy-naïve advanced non-small cell lung cancer of squamous cell histology (Protocol Version Date 10/23/20)

VI Continuing Review

10317, A Pilot Study of Nivolumab in Combination with Decitabine and Venetoclax in TP53-mutated Acute Myeloid Leukemia (Protocol Version Date 01/30/20)

VII New Study - Initial Review

10399, A Phase 1 Study of Entinostat in Combination with Atezolizumab / Carboplatin / Etoposide in Previously Untreated Extensive-Stage Small Cell Lung Cancer (Protocol Version Date 10/20/20)

VIII New Study - Initial Review

10422, A Phase 1/1b Dose Escalation Study of Abemaciclib and Olaparib for Recurrent Platinum-Resistant Ovarian Cancer (Protocol Version Date 09/30/20)

IX Amendment

10096, A Phase 1/2 Study of Combination Olaparib and Radium-223 in Men with Metastatic Castration-Resistant Prostate Cancer with Bone Metastases (COMRADE) (Protocol Version Date 10/28/20)

X Amendment

10126, A Pilot Phase I Study of Atezolizumab (MPDL3280A) in Combination with Immunogenic Chemotherapy (Gemcitabine-Oxaliplatin) and Rituximab for Transformed Diffuse Large B-Cell Lymphoma (Protocol Version Date 10/29/20)

XI Amendment

10183, A Pilot Study of Tazemetostat and MK-3475 (Pembrolizumab) in Advanced Urothelial Carcinoma (Protocol Version Date 10/14/20)

XII Amendment

10291, A Phase 1b Study of M6620 in Combination with Radiation Therapy to Overcome Therapeutic Resistance in Chemotherapy Resistant Triple Negative and Estrogen and/or Progesterone Receptor Positive, HER2 Negative Breast Cancer (Protocol Version Date 10/27/20)
