

Adult CIRB - Early Phase Emphasis Meeting Agenda

January 7, 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 11/25/19)

II Continuing Review

10017, A Randomized Phase 2 Trial of Atezolizumab (MPDL3280A), SGI-110 and CDX-1401 Vaccine in Recurrent Ovarian Cancer (Protocol Version Date 04/11/19)

III 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 10/10/19)

IV Continuing Review

10067, A randomized phase 2 trial of cediranib and olaparib compared to bevacizumab in patients with recurrent glioblastoma who have not received prior VEGF therapy (Protocol Version Date 05/10/19)

V Continuing Review

10246, A Phase 1 Study of MLN4924 (pevonedistat) and Belinostat in Relapsed/Refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome (Protocol Version Date 09/19/19)

VI Continuing Review

9944, Phase 2 Study of M6620 (VX-970) in Combination with gemcitabine versus gemcitabine alone in Subjects with Platinum-Resistant Recurrent Ovarian or Primary Peritoneal Fallopian Tube Cancer (Protocol Version Date 06/04/19)

VII New Study - Initial Review

10300, BLockade of PD-1 Added to Standard Therapy to target Measurable Residual Disease in Acute Myeloid Leukemia 1 (BLAST MRD AML-1): A Randomized Phase 2 Study of the Anti-PD-1 Antibody Pembrolizumab in Combination with Conventional Intensive Chemotherapy as Frontline Therapy in Patients with Acute Myeloid Leukemia (Protocol Version Date 12/03/19)

VIII New Study - Initial Review

10329, Phase I Sequential Trial of Agents Against DNA Repair (STAR) (Protocol Version Date 11/13/19)

IX New Study - Initial Review

10367, A phase 1b study with expansion cohort of escalating doses of KRT-232 (AMG 232) administered in combination with standard induction chemotherapy (cytarabine and idarubicin) in newly diagnosed acute myelogenous leukemia (AML) (Protocol Version Date 11/13/19)
