

Adult CIRB - Early Phase Emphasis Meeting Agenda

November 16, 2021

I Amendment Prior to Activation

AMC-110, Risk-Adapted Therapy for HIV-Associated Anal Cancer (Protocol Version Date 10/19/21)

II Continuing Review

10195, A Phase 2 Study of Copanlisib (BAY 80-6946) in Combination with Fulvestrant in Patients with Metastatic Breast Cancer Progressing After Aromatase Inhibitor Plus CDK 4/6 Inhibitor (Protocol Version Date 12/19/19)

III Continuing Review

10208, A Phase I study of Anetumab Ravtansine in Combination with either Anti-PD-1 Antibody, or Anti-CTLA4 and Anti-PD-1 Antibodies or Anti-PD-1 Antibody and Gemcitabine in Mesothelin-Positive Advanced Pancreatic Adenocarcinoma (Protocol Version Date 05/20/21)

IV Continuing Review

10249, MLN9708 (Ixazomib) and MLN4924 (Pevonedistat) in Relapsed/Refractory Multiple Myeloma Patients: A Phase 1b Trial (Protocol Version Date 08/23/21)

V Continuing 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 10/24/20)

VI Continuing Review

10335, A Phase 1 Study of Lenalidomide in Combination with EPOCH Chemotherapy for HTLV-Associated Adult T-Cell Leukemia-Lymphoma (ATLL) (Protocol Version Date 02/08/21)

VII Continuing 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 04/21/21)

VIII Continuing Review

10403, Phase 1 Trial of Gemcitabine Combined with the BAY 1895344 ATR Inhibitor with Expansion Cohorts in Advanced Pancreatic and Ovarian Cancer (Protocol Version Date 05/10/21)

IX Continuing Review

10422, A Phase 1/1b Dose Escalation Study of Abemaciclib and Olaparib for Recurrent Platinum-Resistant Ovarian Cancer (Protocol Version Date 09/03/21)
