

Adult CIRB - Early Phase Emphasis Meeting Agenda

October 18, 2022

I New Study - Initial Review

A092106, Phase I/II Study of BET and MEK Inhibition in Advanced Uveal Melanoma (Version Date 09/06/22)

II 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 (Version Date 10/11/21)

III Continuing Review

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

IV Continuing Review

10449, A Phase 1 Study of ZEN003694 in Combination with Binimetinib in Solid Tumors with RAS Pathway Alterations and Triple Negative Breast Cancer (Version Date 01/06/22)

V Continuing Review

10422, A Phase 1/1b Dose Escalation Study of Abemaciclib and Olaparib for Recurrent Platinum-Resistant Ovarian Cancer (Version Date 07/20/22)

VI 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) (Version Date 12/21/21)



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VII Continuing Review

10403, Phase 1 Trial of Gemcitabine Combined with the BAY 1895344 ATR Inhibitor with Expansion Cohorts in Advanced Pancreatic and Ovarian Cancer (Version Date 05/12/22)

VIII 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 (Version Date 02/04/22)
