

Adult CIRB - Early Phase Emphasis Meeting Agenda

September 3, 2024

I Amendment Prior to Activation

10237, A Phase 1 Study of TAK-243 for Relapsed or Refractory Acute Myeloid Leukemia or Myelodysplastic Syndromes with Increased Blasts (Version Date 07/22/24)

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 05/28/24)

III Continuing Review

10358, Phase 1/1B study of DS-8201a in combination with ATR Inhibition (AZD6738) in advanced solid tumors with HER2 expression (DASH Trial) (Version Date 03/18/24)

IV Continuing Review

10217, A Phase 1b Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients with Advanced Solid Tumors (Version Date 05/13/24)

V Continuing Review

EAY191-E4, A ComboMATCH Treatment Trial ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients with Prior Taxane-Treated Solid Tumors (Version Date 12/20/23)

VI Continuing Review

EAY191-A3, A ComboMATCH Treatment Trial: Palbociclib and Binimetinib in RAS-Mutant Cancers (Version Date 05/16/24)

VII Continuing Review

10347, A phase I study with an expansion cohort of duvelisib and nivolumab in mycosis fungoides (MF) and Sézary syndrome (SS) (Version Date 08/22/23)

VIII Continuing Review

10075, A Phase 1B Study of KRT-232 (AMG-232) in Combination with Decitabine and Venetoclax in Acute Myeloid Leukemia (Version Date 01/04/24)

IX Continuing Review

10327, A Phase 1 Trial of MLN0128 (sapanisertib) and Telaglenastat (CB-839) HCl in Advanced NSCLC Patients (Version Date 12/19/23)
