

Adult CIRB - Early Phase Emphasis Meeting Agenda

October 3, 2023

I New Study - Initial Review

10608, A Phase II Trial of Durvalumab with Gemcitabine and Cisplatin as Neoadjuvant Therapy for High-Risk Resectable Intrahepatic Cholangiocarcinoma (Version Date 08/04/23)

II Amendment

10558, A Phase II Randomized Control Trial of Triapine Plus Lutetium Lu 177 Dotatate Versus Lutetium Lu 177 Dotatate Alone for Well-Differentiated Somatostatin Receptor-Positive Neuroendocrine Tumors (Version Date 08/18/23)

III Amendment

10335, A Phase 1 Study of Lenalidomide in Combination with EPOCH Chemotherapy for HTLV-Associated Adult T-Cell Leukemia-Lymphoma (ATLL) (Version Date 08/03/23)

IV Continuing Review

10216, A Phase Ib Study of Osimertinib (AZD9291) and Telaglenastat (CB-839) HCl in Patients with EGFR Mutant Non-Small Cell Lung Cancer (Version Date 05/02/23)

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 (Version Date 04/11/23)

VI Continuing Review

10061, A Phase 1 Study of Pembrolizumab (MK-3475) in Combination with Recombinant Interleukin-12 in Patients with Solid Tumors (Version Date 02/23/23)

VII Continuing Review

10075, A Phase 1B Study of KRT-232 (AMG-232) in Combination with Decitabine and Venetoclax in Acute Myeloid Leukemia (Version Date 04/04/23)

VIII Continuing Review

10327, A Phase 1 Trial of MLN0128 (sapanisertib) and Telaglenastat (CB-839) HCl in Advanced NSCLC Patients (Version Date 07/31/23)

IX 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 07/11/23)
