

Adult CIRB - Early Phase Emphasis Meeting Agenda

April 5, 2022

I Continuing Review

10014, A Pilot Study of Atezolizumab (MPDL3280A) Following Adoptive Cell Transfer in Active Hematologic or Solid Tumor Malignancies (Protocol Version Date 03/07/22)

II Continuing Review

10139, A Randomized Phase 2 Study of Atezolizumab in Combination with Cobimetinib versus Atezolizumab Monotherapy in Participants with Unresectable Cholangiocarcinoma (Protocol Version Date 07/01/21)

III Continuing Review

10146, Randomized phase 2 clinical trial of nab-paclitaxel + durvalumab (MEDI4736) + tremelimumab + neoantigen vaccine vs. nab-paclitaxel + durvalumab (MEDI4736) + tremelimumab in patients with metastatic triple negative breast cancer (Protocol Version Date 11/03/21)

III Continuing Review

10219, Phase I Dose-Escalation and Dose-Expansion Trial of a Novel Glutaminase Inhibitor Telaglenastat (CB-839) HCl in Combination with Carfilzomib and Dexamethasone in Relapsed and/or Refractory Multiple Myeloma (Protocol Version Date 10/07/21)

IV Continuing Review

10273, A Phase 1 Study of M3814 in combination with MEC in Patients with Relapsed or Refractory Acute Myeloid Leukemia (Protocol Version Date 11/01/21)

V Continuing Review

9881, A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors (Protocol Version Date 09/07/21)

VI Continuing Review

9903, A Phase 1B Study of AZD9291 in Combination with Navitoclax in EGFR-mutant Non-Small Cell Lung Cancer Following Resistance to Initial EGFR Kinase Inhibitor (Protocol Version Date 01/06/22)

VII Continuing Review

9984, A Randomized Phase 2 Study of cediranib in Combination with olaparib versus olaparib alone in men with metastatic castration resistant prostate cancer (Protocol Version Date 09/07/21)

VIII Continuing Review

EA5162, Phase II Study of AZD9291 (Osimertinib) in Advanced NSCLC Patients with Exon 20 Insertion Mutations in EGFR (Protocol Version Date 06/29/20)

IX New Study - Initial Review

10495, Phase I Trial of DS-8201a (Trastuzumab Deruxtecan) in Combination with Neratinib in Solid Tumors with HER2 Alterations (Protocol Version Date 02/16/22)

X New Study - Initial Review

10508, A Phase 1 Study of Nivolumab in Combination with ASTX727 in B-cell lymphoma (NHL or HL) with an Expansion Cohort in Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL) (Protocol Version Date 01/25/22)

XI Amendment

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 02/04/22)

XII Amendment

10246, A Phase 1 Study of MLN4924 (pevonedistat) and Belinostat in Relapsed/Refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome (Protocol Version Date 02/16/22)

XIII Amendment

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 03/07/22)
