

Adult CIRB - Early Phase Emphasis Meeting Agenda

March 7, 2023

I Amendment

10406, Phase 1/1b Trial of ATR Inhibitor BAY 1895344 in Combination with FOLFIRI in GI Malignancies with a Focus on Metastatic Colorectal and Gastric/Gastroesophageal Cancers (Version Date 01/27/23)

II Continuing Review

10014, A Pilot Study of Atezolizumab (MPDL3280A) Following Adoptive Cell Transfer in Active Hematologic or Solid Tumor Malignancies (Version Date 11/02/22)

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 (Version Date 01/24/23)

IV Continuing Review

10507, A Phase 1/2 Study of the Bromodomain Inhibitor ZEN003694 in Combination with Etoposide/Platinum in Patients with NUT Carcinoma (Version Date 06/28/22)

V Continuing Review

10509, A Phase 1 Study of BET Bromodomain Inhibitor ZEN003694 in Combination with the CDK4/6 Inhibitor Abemaciclib in Patients with NUT Carcinoma and Other Solid Tumors (Version Date 06/03/22)

VI Continuing Review

EA5162, Phase II Study of AZD9291 (Osimertinib) in Advanced NSCLC Patients with Exon 20 Insertion Mutations in EGFR (Version Date 03/10/22)

VII 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 (Version Date 06/15/22)

VIII Continuing Review

10287, A randomized Phase I/II trial of fulvestrant and abemaciclib in combination with copanlisib (FAC) versus fulvestrant and abemaciclib alone (FA) for endocrine-resistant, hormone receptor positive, HER2 negative metastatic breast cancer (FAC vs FA) (Version Date 10/08/21)

IX Continuing Review

10139, A Randomized Phase 2 Study of Atezolizumab in Combination with Cobimetinib versus Atezolizumab Monotherapy in Participants with Unresectable Cholangiocarcinoma (Version Date 10/10/22)
