

Adult CIRB - Early Phase Emphasis Meeting Agenda

February 6, 2024

I 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 03/01/23)

II 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 11/02/23)

III 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 12/21/23)

IV Continuing Review

10561, Rapid Analysis and Response Evaluation of Combination Anti-neoplastic Agents in Rare Tumors (RARE CANCER) Trial: RARE 3 Tiragolumab + Atezolizumab (Version Date 11/16/23)

V Continuing Review

EA5162, Phase II Study of Osimertinib (AZD9291) in Advanced NSCLC Patients with Exon 20 Insertion Mutations in EGFR (Version Date 03/28/23)

VI 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)

VII 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 11/28/23)
