

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 7, 2021

I Continuing Review

10061, A Phase 1 Study of Pembrolizumab (MK-3475) in Combination with Recombinant Interleukin-12 in Patients with Solid Tumors (Protocol Version Date 10/11/21)

II Continuing Review

10216, A Phase Ib Study of AZD9291 (Osimertinib) and CB-839 HCl in Patients with EGFR Mutant Non-Small Cell Lung Cancer (Protocol Version Date 03/03/21)

III Continuing Review

10347, A phase I study with an expansion cohort of duvelisib and nivolumab in mycosis fungoides (MF) and Sézary syndrome (SS) (Protocol Version Date 02/05/21)

IV Continuing Review

9950, A Phase I Study of M6620 (VX-970, berzosertib) in Combination with Cisplatin and XRT in Patients with Locally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC; SDC 10060121) (Protocol Version Date 11/09/21)

V New Study - Initial Review

10490, Rapid Analysis and Response Evaluation of Combination Anti-neoplastic Agents in Rare Tumors (RARE CANCER) Trial: RARE 2 Talazoparib and Temozolomide (Protocol Version Date 11/04/21)

VI Amendment

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)

VII Amendment

10434, Randomized Phase 2 Study of CPX-351 + Pomalidomide versus CPX-351 in Newly Diagnosed AML with MDS-Related Changes (Protocol Version Date 11/08/21)
