

Adult CIRB - Early Phase Emphasis Meeting Agenda

June 16, 2020

I Continuing Review

10146, Randomized phase 2 clinical trial of nab-paclitaxel + MEDI4736 (durvalumab) + tremelimumab + neoantigen vaccine vs. nab-paclitaxel + MEDI4736 (durvalumab) + tremelimumab in patients with metastatic triple negative breast cancer (Protocol Version Date 01/14/19)

II Continuing Review

10219, Phase I Dose-Escalation and Dose-Expansion Trial of a Novel Glutaminase Inhibitor (CB-839 HCl) in Combination with Carfilzomib and Dexamethasone in Relapsed and/or Refractory Multiple Myeloma (Protocol Version Date 10/07/19)

III 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 09/03/19)

IV 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) (Protocol Version Date 03/17/20)
