

Adult CIRB - Early Phase Emphasis Meeting Agenda

May 18, 2021

I 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 06/11/20)

II 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 02/15/21)

III 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 07/24/20)

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 10/05/20)

V 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 09/11/20)



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VI Continuing Review

10410, A Phase 1 Study of IPdR in Combination with Capecitabine and Radiotherapy in Rectal Cancer (Protocol Version Date 07/30/20)

VII New Study ReReview

10417, Clinical Evaluation of ASTX727 in Combination with Venetoclax All-Oral Therapy vs. Standard of Care Cytarabine and Anthracycline Induction Chemotherapy for Younger FLT3WT Patients with ELN High- Risk Acute Myeloid Leukemia (Protocol Version Date 04/30/21)

VIII Amendment

10330, A Phase 2 Study of Belinostat and SGI-110 (Guadecitabine) or ASTX727 for the Treatment of Unresectable and Metastatic Conventional Chondrosarcoma (Protocol Version Date 04/02/21)

IX Amendment

10402, BAY 1895344 Plus Topoisomerase-1 (Top1) Inhibitors in Patients with Advanced Solid Tumors, Phase I Studies with Expansion Cohorts in Small Cell Lung Carcinoma (SCLC), Poorly Differentiated Neuroendocrine Carcinoma (PD-NEC) and Pancreatic Adenocarcinoma (PDA) (Protocol Version Date 04/05/21)
