

**Adult CIRB - Early Phase Emphasis Meeting Agenda**

**April 6, 2021**

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**I Continuing Review**

**10382**, A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination with Copanlisib in Patients with Metastatic Triple Negative Breast Cancer (Protocol Version Date 07/09/20)

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**II Continuing Review**

**9466**, Phase I/II study of dabrafenib, trametinib, and navitoclax in BRAF mutant melanoma (Phase I and II) and other solid tumors (Phase I only) (Protocol Version Date 03/08/21)

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**III Continuing Review**

**9706**, Randomized phase II study to assess the role of Nivolumab as single agent to eliminate minimal residual disease and maintain remission in acute myelogenous leukemia (AML) patients after chemotherapy (REMAIN Trial) (Protocol Version Date 03/12/21)

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**IV Continuing Review**

**9898**, A Phase I Trial of AZD9291 and Nectinumab in EGFR-Mutant Non-Small Cell Lung Cancer After Progression on a Previous EGFR Tyrosine Kinase Inhibitor (Protocol Version Date 12/07/20)

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**V Continuing Review**

**S1320**, A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma (Protocol Version Date 06/18/20)

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## **VI New Study - Initial Review**

**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 02/24/21)

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## **VII New Study - Initial Review**

**10434**, Randomized Phase 2 Study of CPX-351 + Pomalidomide versus CPX-351 in Newly Diagnosed AML with MDS-Related Changes (Protocol Version Date 02/10/21)

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## **VIII Amendment**

**10268**, Randomized Phase II Trial of Topotecan plus M6620 (VX-970) vs. Topotecan alone in Patients with Relapsed Small-Cell Lung Cancer (Protocol Version Date 02/16/21)

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## **IX Amendment**

**10399**, A Phase 1 Study of Entinostat in Combination with Atezolizumab / Carboplatin / Etoposide in Previously Untreated Extensive-Stage Small Cell Lung Cancer (Protocol Version Date 02/12/21)

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## **X Memos**

**EAY131**, Molecular Analysis for Therapy Choice (MATCH) (Protocol Version Date )

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