

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

**April 20, 2021**

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### **I Continuing Review**

**10070**, Phase 1/2 Study of Navitoclax Plus Vistusertib in Patients with Relapsed Small Cell Lung Cancer (SCLC) and Other Solid Tumors (Protocol Version Date 03/02/21)

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### **II Continuing Review**

**10191**, A Phase 2 Study of M6620 in Combination with Carboplatin compared with Docetaxel in Combination with Carboplatin in Metastatic Castration-Resistant Prostate Cancer (Protocol Version Date 02/01/21)

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### **III Continuing Review**

**10264**, The PRIME Trial: PARP Inhibition in IDH Mutant Effectiveness Trial. A Phase II Study of Olaparib in Isocitrate Dehydrogenase (IDH) Mutant Relapsed/Refractory Acute Myeloid Leukemia and Myelodysplastic Syndrome (Protocol Version Date 09/08/20)

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### **IV Continuing Review**

**10266**, A Phase 2 Study of MLN4924 (pevonedistat) in Combination with Carboplatin and Paclitaxel in Advanced NSCLC Previously Treated with Immunotherapy (Protocol Version Date 03/03/21)

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### **V Continuing Review**

**ABTC-1701**, Pilot Surgical PK Study of Bemcentinib in Recurrent Glioblastoma Patients (Protocol Version Date 08/07/20)

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

**10433**, Phase I/Ib trial evaluating the safety and efficacy of BET inhibitor, ZEN003694 with PD-1 inhibitor, nivolumab with or without CTLA-4 inhibitor, ipilimumab in solid tumors (Protocol Version Date 03/02/21)

**VII New Study - Initial Review**

**10440**, A Phase 1/1a Study of Venetoclax, MLN9708 (ixazomib citrate) and Dexamethasone for Relapsed/Refractory Light Chain Amyloidosis (Protocol Version Date 03/25/21)

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**VIII Amendment**

**10367**, A Phase 1b Study with Expansion Cohort of Escalating Doses of KRT-232 (AMG 232) Administered in Combination with Standard Induction Chemotherapy (Cytarabine and Idarubicin) in Newly Diagnosed Acute Myelogenous Leukemia (AML) (Protocol Version Date 03/09/21)

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**IX Amendment**

**9950**, A Phase I Study of M6620 (VX-970) in Combination with Cisplatin and XRT in Patients with Locally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC; SDC 10060121) (Protocol Version Date 03/23/21)

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