

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

**March 15, 2022**

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### **I 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 08/30/21)

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### **II 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 12/20/21)

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### **III New Study - Initial Review**

**10509**, A Phase 1 Study of BET Bromodomain Inhibitor ZEN003694 in Combination with the CDK4/6 Inhibitor Abemaciclib in Patients with NUT Carcinoma and Other Solid Tumors (Protocol Version Date 01/12/22)

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### **IV Amendment**

**10005**, A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Alveolar Soft Part Sarcoma (Protocol Version Date 02/03/22)

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### **V Amendment**

**10096**, A Phase 1/2 Study of Combination Olaparib and Radium-223 in Men with Metastatic Castration-Resistant Prostate Cancer with Bone Metastases (COMRADE) (Protocol Version Date 12/10/21)

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### **VI Amendment**

**10144**, A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma and other genitourinary tumors with DNA-Repair Defects (Protocol Version Date 01/05/22)

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**VI Amendment**

**10329**, Phase I Sequential Trial of Agents Against DNA Repair (STAR) (Protocol Version  
Date 02/021/22)

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