Adult CIRB - Early Phase Emphasis Meeting Agenda
March 15, 2022

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)

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)

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)

IV  Amendment

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

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)

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)
VI Amendment

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