

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

**March 3, 2020**

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**I Continuing Review**

**10020**, A Phase II Open-Label, Randomized Study of PARP Inhibition (olaparib) Either Alone or in Combination with Anti-PD-L1 Therapy (atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-positive Breast Cancer (Protocol Version Date 05/24/19)

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**II Continuing Review**

**10031**, A Phase 1 Study of PARP inhibitor olaparib and HSP90 inhibitor AT13387 for treatment of advanced solid tumors with expansion in patients with recurrent epithelial ovarian, fallopian tube, peritoneal cancer or recurrent triple-negative breast cancer (Protocol Version Date 12/13/19)

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**III Continuing Review**

**10066**, A Phase 1 / 2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma (Protocol Version Date 05/29/19)

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**IV Continuing Review**

**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 11/30/19)

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**V Continuing Review**

**10144**, A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma with DNA-Repair Defects (Protocol Version Date 01/06/20)

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**VI Continuing Review**

**10166**, A Phase 2 Study of Atezolizumab and Cobimetinib in PD-1/PD-L1 Inhibitor Resistant or Refractory Non-Small Cell Lung Cancer (Protocol Version Date 05/29/19)

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**VII Continuing Review**

**10183**, A Pilot Study of Tazemetostat and MK-3475 (Pembrolizumab) in Advanced Urothelial Carcinoma (Protocol Version Date 01/09/20)

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**VIII Continuing Review**

**10250**, A Phase II Study of the PARP Inhibitor Olaparib in Combination with the DNA Damaging Agent Temozolomide for the Treatment of Advanced Uterine Leiomyosarcoma (Protocol Version Date 07/02/19)

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**IX New Study - Initial Review**

**10334**, BLockade of PD-1 Added to Standard Therapy to target Measurable Residual Disease in Acute Myeloid Leukemia 2 (BLAST MRD AML-2): A randomized Phase 2 Study of the Venetoclax, Azacitidine, and Pembrolizumab (VAP) Versus Venetoclax and Azacitidine as First Line Therapy in Older Patients with Acute Myeloid Leukemia (AML) who are Ineligible or who Refuse Intensive Chemotherapy (Protocol Version Date 01/31/20)

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**X New Study - Initial Review**

**10349**, A Phase 1 Trial of the p97 Inhibitor CB-5339 in Patients With Advanced Solid Tumors and Lymphomas (Protocol Version Date 02/03/20)

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