

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

**January 4, 2022**

---

### **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 09/08/21)

---

### **II Continuing Review**

**10066**, A Phase 1 / 2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma (Protocol Version Date 09/13/21)

---

### **III 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 08/26/21)

---

### **IV Continuing Review**

**10144**, A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma with DNA-Repair Defects (Protocol Version Date 08/27/21)

---

### **V 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 09/01/21)

---

### **VI Continuing Review**

**10183**, A Pilot Study of Tazemetostat and Pembrolizumab (MK-3475) in Advanced Urothelial Carcinoma (Protocol Version Date 10/06/21)

---

## **VII 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 09/14/21)

---

## **VIII Continuing 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 10/11/21)

---

## **IX New Study - Initial Review**

**10492**, Phase 1/1b Study of AKT Inhibitor Ipatasertib with Chemoradiation for Locally Advanced Head and Neck Cancer (Protocol Version Date 09/02/21)

---

## **X New Study - Initial Review**

**10496**, A Phase 2 Study of Ipatasertib in Combination with Pembrolizumab for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (Protocol Version Date 09/02/21)

---

## **XI Amendment**

**10346**, Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-expressing Advanced Solid Tumors (Protocol Version Date 11/19/21)

---