

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

**November 17, 2020**

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**I Continuing Review**

**10026**, A Phase 1 Study of Ipilimumab in Combination with Decitabine in Relapsed or Refractory Myelodysplastic Syndrome/Acute Myeloid Leukemia (Protocol Version Date 06/30/20)

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**II Continuing Review**

**10131**, A Phase 1 Study of AZD8186 in Combination with Docetaxel in patients with PTEN mutated or PIK3CB mutated advanced solid tumors, potentially amenable to docetaxel (Protocol Version Date 12/03/19)

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**III Continuing Review**

**10366**, A Phase 1/2 Study of M3814 (peposertib) in Combination with Hypofractionated Radiotherapy for the Treatment of Locally Advanced Pancreatic Adenocarcinoma (Protocol Version Date 09/08/20)

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**IV New Study ReReview**

**10406**, Phase 1/1b Trial of ATR Inhibitor BAY 1895344 in Combination with FOLFIRI in GI Malignancies with a Focus on Metastatic Colorectal and Gastric/Gastroesophageal Cancers (Protocol Version Date 10/30/20)

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**V New Study - Initial Review**

**10403**, Phase 1 Trial of Gemcitabine Combined with the BAY 1895344 ATR Inhibitor with Expansion Cohorts in Advanced Pancreatic and Ovarian Cancer (Protocol Version



FOR THE NATIONAL CANCER INSTITUTE

Date 10/05/20)

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

**10437**, A Single Arm Phase II Study of Bone-targeted Sn-117m-DTPA in Symptomatic Castration Resistant Prostate Cancer with Skeletal Metastases (Protocol Version Date 10/08/20)

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## **VII Amendment ReReview**

**9892**, Phase I Dose-Escalation Bioavailability Study of Oral Triapine in Combination with Concurrent Chemoradiation for Locally Advanced Cervical Cancer (LACC) and Vaginal Cancer (Protocol Version Date 11/03/20)

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## **VIII Amendment**

**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 09/25/20)

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## **IX Memos**

**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 08/31/20)

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