

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

**December 20, 2022**

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**I New Study - Initial Review**

**10527**, A Molecularly Driven Phase 1b Dose Escalation and Dose Expansion Study of the DNA-PK Inhibitor Peposertib (M3814) in Combination with the ATR Inhibitor M1774 (Version Date 11/18/22)

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**II New Study - Initial Review**

**EAY191-E5**, A ComboMATCH Treatment Trial ComboMATCH Treatment Trial E5: A Randomized Phase II Study of AMG 510 (Sotorasib) with or without Panitumumab in Advanced Solid Tumors (Version Date 10/25/22)

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**III New Study - Initial Review**

**10572**, A Phase 1/2 Trial Evaluating the Combination of Temozolomide and the Ataxia Telangiectasia and Rad3-related Inhibitor M1774 (Version Date 11/18/22)

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**IV Continuing Review**

**10346**, Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-expressing Advanced Solid Tumors (Version Date 10/12/22)

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**V 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) (Version Date 12/10/21)

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## **VI Continuing Review**

**10220**, A Phase II Basket Trial of Glutaminase Inhibitor (BeGIN) Telaglenastat (CB-839) HCl in Patients with NF1 Aberrations, NF1 Mutant Malignant Peripheral Nerve Sheath Tumors (MPNST), KEAP1/NRF2 and LKB1 Aberrant Tumors (Version Date 09/07/21)

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## **VII Continuing Review**

**CITN-17**, Phase 1 Study of NT-I7 (rhIL-7-hyFc) for the Treatment of Kaposi Sarcoma in Patients With or Without Infection with HIV (Version Date 10/15/21)

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## **VIII Continuing Review**

**10150**, A randomized phase 2 study of bevacizumab and either weekly anetumab raptansine or weekly paclitaxel in platinum-resistant or platinum refractory ovarian cancer (Version Date 07/28/21)

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## **IX Continuing Review**

**10313**, A phase IB and randomized open-label phase II study of Berzosertib (M6620, VX-970) in combination with carboplatin/gemcitabine/pembrolizumab in patients with chemotherapy-naïve advanced non-small cell lung cancer of squamous cell histology (Version Date 10/21/22)

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## **X 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 (Version Date 10/25/22)

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## **XI Continuing Review**

**10292**, DURVA+ : Evaluation of the Safety and Pharmacodynamics of Anti-PD-L1 Antibody Durvalumab in Combination with Chemotherapy in Patients with Advanced Solid Tumors (Version Date 01/13/22)

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## **XII Continuing Review**

**10450**, A Phase 1b Trial of M3814 (Peposertib) in Combination with Lutetium 177 Dotatate for Well-Differentiated Somatostatin Receptor-Positive Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Version Date 12/02/22)

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## **XIII Continuing Review**

**10268**, Randomized Phase II Trial of Topotecan plus M6620 (VX-970, Berzosertib) vs. Topotecan alone in Patients with Relapsed Small-Cell Lung Cancer (Version Date 10/21/22)

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## **XIV Continuing Review**

**10089**, A Randomized Phase 2 Study of CDX-1127 (Varlilumab) in Combination with Nivolumab in Patients with Relapsed or Refractory Aggressive B-cell Lymphomas (Version Date 02/17/21)

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