

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

**September 6, 2022**

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**I Continuing Review**

**10030**, A phase 1 study of blinatumomab in combination with checkpoint inhibitor(s) of PD-1 (nivolumab) or both PD-1 (nivolumab) and CTLA-4 (ipilimumab) in patients with poor-risk, relapsed or refractory CD19+ precursor B-lymphoblastic leukemia (Protocol Version Date 01/28/21)

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**II Continuing Review**

**10042**, A Phase II trial of AZD9291 (osimertinib) with or without bevacizumab in patients with EGFR mutation positive NSCLC and brain metastases (Protocol Version Date 12/11/20)

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**III Continuing Review**

**10056**, A Phase 2 Study of Talimogene Laherparepvec (T-VEC) and Radiation in Localized Soft Tissue Sarcoma (Protocol Version Date 05/25/22)

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**IV Continuing Review**

**10214**, Immune Checkpoint Blockade for Kidney Transplant Recipients with Selected Unresectable or Metastatic Cancers (Protocol Version Date 01/28/21)

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**V Continuing Review**

**10285**, Phase 1/2 Study of an EZH2 inhibitor (tazemetostat) in combination with dual BRAF/MEK inhibition in patients with BRAF-mutated metastatic melanoma who progressed on prior BRAF/MEK inhibitor therapy (Protocol Version Date 03/18/22)

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**VI Continuing Review**

**10355**, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Protocol Version Date 04/13/22)

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**VII Continuing Review**

**10371**, A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response (Protocol Version Date 06/01/22)

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**VIII New Study - Initial Review**

**10528**, A Phase 1 Study of the Polymerase Theta (POL $\theta$ ) Inhibitor Novobiocin in BRCA-mutant and Other DNA Damage Repair-Deficient Solid Tumors (Protocol Version Date 07/25/22)

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**IX New Study - Initial Review**

**EAY191**, Molecular Analysis for Combination Therapy Choice (ComboMATCH) (Protocol Version Date 08/01/22)

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**X New Study - Initial Review**

**EAY191-N4**, Molecular Analysis for Combination Therapy Choice (ComboMATCH) EAY191-N4: A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers A ComboMATCH Treatment Trial (Protocol Version Date 08/02/22)

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