

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

**August 19, 2025**

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**I New Study - Initial Review**

**10720**, Phase 1b study of Pidnarulex and Trastuzumab Deruxtecan in patients with HER2 expressing Solid Tumors (Version Date 07/21/25)

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**II 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 (Version Date 03/10/25)

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**III Continuing Review**

**10144**, A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma and other genitourinary tumors with DNA-Repair Defects (Version Date 02/28/24)

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**IV 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 (Version Date 02/26/25)

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**V Continuing Review**

**10346**, Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-expressing Advanced Solid Tumors (Version Date 11/26/24)

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## **VI Continuing Review**

**10490**, Rapid Analysis and Response Evaluation of Combination Anti-neoplastic Agents in Rare Tumors (RARE CANCER) Trial: RARE 2 Talazoparib and Temozolomide (Version Date 12/16/24)

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## **VII Continuing Review**

**10528**, A Phase 1 Study of the Polymerase Theta (POLθ) Inhibitor Novobiocin in BRCA-mutant and Other DNA Damage Repair-Deficient Solid Tumors (Version Date 07/01/25)

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## **VIII Continuing Review**

**10538**, Venetoclax In Combination with ASTX727, an All-ORal Therapy for Chronic Myelomonocytic Leukemia and Other MDS/MPN with Excess Blasts (VICTORY-MDS/MPN): a Randomized, Phase 2 trial (Version Date 03/12/25)

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## **IX 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 (Version Date 01/27/25)

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## **X Continuing Review**

**10608**, A Phase II Trial of Durvalumab with Gemcitabine and Cisplatin as Neoadjuvant Therapy for High-Risk Resectable Intrahepatic Cholangiocarcinoma (Version Date 03/05/25)

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## **XI Continuing Review**

**10347**, A phase I study with an expansion cohort of duvelisib and nivolumab in mycosis fungoides (MF) and Sézary syndrome (SS) (Version Date 11/04/24)

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