

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

**October 17, 2023**

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**I New Study - Initial Review**

**10612**, A Randomized Phase 2 Study of Daratumumab-Selinexor-Velcade-Dexamethasone (Dara-SVD) for High-Risk Newly Diagnosed Multiple Myeloma (Version Date 08/31/23)

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**II Amendment**

**10402**, BAY 1895344 Plus Topoisomerase-1 (Top1) Inhibitors in Patients with Advanced Solid Tumors, Phase I Studies with Expansion Cohorts in Small Cell Lung Carcinoma (SCLC), Poorly Differentiated Neuroendocrine Carcinoma (PD-NEC) and Pancreatic Adenocarcinoma (PDA) (Version Date 09/01/23)

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**III Continuing Review**

**10076**, A Phase 1 Dose-Escalation and Exploratory Dose Expansion Study of KRT-232 (AMG 232) in Combination with Carfilzomib, Lenalidomide, and Dexamethasone in Relapsed and/or Refractory Myeloma (Version Date 01/24/22)

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**IV Continuing Review**

**10217**, A Phase 1b Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients with Advanced Solid Tumors (Version Date 07/20/23)

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**V 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 08/22/23)

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## **VI Continuing Review**

**10358**, Phase 1/1B study of DS-8201a in combination with ATR Inhibition (AZD6738) in advanced solid tumors with HER2 expression (DASH Trial) (Version Date 02/17/22)

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## **VII 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 09/12/23)

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## **VIII Continuing 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 (Version Date 03/08/23)

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