

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

**May 16, 2023**

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**I New Study - Initial Review**

**10603**, A Phase 2 Study of M1774 in Refractory SPOP-mutant Prostate Cancer (Version Date 03/29/23)

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**II New Study - Initial Review**

**NRG-GY031**, A Phase 1B Study of Combination ATR (M1774) and BET Inhibition (ZEN00-3694) to Exploit ARID1A Loss in Recurrent Ovarian and Endometrial Cancer (Version Date 04/07/23)

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**III Amendment**

**10075**, A Phase 1B Study of KRT-232 (AMG-232) in Combination with Decitabine and Venetoclax in Acute Myeloid Leukemia (Version Date 04/04/23)

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**IV Continuing Review**

**10005**, A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Alveolar Soft Part Sarcoma (Version Date 10/26/22)

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**V Continuing Review**

**10301**, A Phase I and Randomized Phase II Trial of Radium-223 dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC) (Version Date 05/12/22)

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**VI Continuing Review**

**9938**, Phase I clinical trial of M6620 (VX-970, berzosertib) in combination with the topoisomerase I inhibitor irinotecan in patients with advanced solid tumors (Version Date 08/29/22)

## **VII Continuing Review**

**10100**, A Randomized, Phase 2 Trial to Evaluate the Safety and Efficacy of Eribulin Mesylate in Combination with Atezolizumab Compared to Atezolizumab Alone in Subjects with Locally Advanced or Metastatic Transitional Cell Urothelial Cancer Where Cisplatin-Based Treatment is Not an Option (Version Date 04/17/23)

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## **VIII Continuing Review**

**10387**, Pilot Trial of Nivolumab plus Cabozantinib for Advanced Solid Tumors in Patients with HIV Infection (Version Date 08/18/22)

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## **IX Continuing Review**

**10315**, A Phase 2 Study of XL184 (Cabozantinib) in Combination with Nivolumab and Ipilimumab for the Treatment of Poorly Differentiated Neuroendocrine Carcinomas (Version Date 02/22/21)

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