

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

**April 1, 2025**

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**I New Study - Initial Review**

**10695**, Phase 1 Study of Lintuzumab-Ac225 Monotherapy for Patients with Hypomethylating Agent-Refractory Myelodysplastic Syndrome (Version Date 02/12/25)

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**II Amendment**

**10500**, Phase 1/Expansion Study of Tazemetostat Plus Belinostat for the Treatment of Relapsed or Refractory Lymphoma (Version Date 02/03/25)

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**III Continuing Review**

**10603**, A Phase 2 Study of M1774 in Refractory SPOP-mutant Prostate Cancer (Version Date 09/18/24)

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**IV Continuing Review**

**10487**, A Phase II study of Lutetium Lu 177 dotatate in metastatic prostate cancer with neuroendocrine differentiation (Version Date 12/13/24)

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**V Continuing Review**

**10579**, Phase I trial of ZEN003694 (ZEN-3694) in combination with capecitabine in patients with solid tumors (Version Date 02/19/25)

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**VI Continuing Review**

**10276**, A Phase I/II Study of Peposertib (M3814) and Avelumab in Combination with Hypofractionated Radiation in Patients with Advanced/Metastatic Solid Tumors and Hepatobiliary Malignancies (Version Date 10/30/24)

## **VII Continuing Review**

**10324**, A Phase I/Ib Dose Escalation Study of Pegylated Liposomal Doxorubicin (PLD) With Pepsertib (M3814) in Platinum-Resistant or Ineligible Ovarian and Related Cancers with Planned Expansions in High Grade Serous (HGSOC) and Low Grade Serous Ovarian Cancer (LGSOC) (Version Date 10/10/24)

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## **VIII Continuing Review**

**10433**, Phase I/Ib trial evaluating the safety and efficacy of BET inhibitor, ZEN003694 with PD-1 inhibitor, nivolumab with or without CTLA-4 inhibitor, ipilimumab in solid tumors (Version Date 02/18/25)

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## **IX Continuing Review**

**10556**, Randomized Phase 2 Study of Cabozantinib, Ipilimumab, and Nivolumab in Patients with Soft Tissue Sarcoma (Version Date 12/10/24)

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