

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

**May 21, 2024**

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**I New Study - Initial Review**

**NRG-GY034**, A Randomized Phase 1/2 Trial Evaluating the Addition of Tolinapant to Weekly Paclitaxel with or without Bevacizumab in Patients with Recurrent Epithelial Ovarian Cancer (Version Date 04/05/24)

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**II New Study ReReview**

**10629**, A Phase I Dose Finding and Phase II Randomized Trial of Iadademstat Combined with Immune Checkpoint Inhibition Maintenance After Initial Chemoimmunotherapy in Patients with Extensive-Stage Small Cell Lung Cancer (Version Date 04/04/24)

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**III Amendment**

**10505**, A Phase 1 and Randomized Phase 2 Trial of Selinexor and Temozolomide in Recurrent Glioblastoma (Version Date 04/03/24)

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**IV Amendment**

**A051901**, Phase I Trial of Methotrexate, Rituximab, Lenalidomide, and Nivolumab (NIVO-MR2) Induction Followed by Lenalidomide and Nivolumab Maintenance in Primary CNS Lymphoma (Version Date 04/12/24)

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**V Continuing Review**

**10466**, A Phase 2 Study of Bevacizumab, Erlotinib and Atezolizumab in Subjects with Advanced Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC) Associated or Sporadic Papillary Renal Cell Cancer (Version Date 10/12/23)

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## **VI Continuing Review**

**10525**, A Phase 1b Trial of ZEN003694 (ZEN-3694) with Pembrolizumab and Nab-Paclitaxel in Patients with Metastatic Triple-Negative Breast Cancer (Version Date 12/04/23)

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## **VII Continuing Review**

**10170**, A Phase 2 Study of AZD1775 in SETD2-Deficient Advanced Solid Tumor Malignancies (Version Date 08/24/20)

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## **VIII Continuing 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 08/14/23)

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