

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

**January 3, 2023**

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**I New Study - Initial Review**

**10299**, A Phase I Study to Investigate the Safety of the Ubiquitin Activating Enzyme Inhibitor TAK-243 in Adult Solid Tumor and Lymphoma Patients (Version Date 11/07/22)

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**II New Study - Initial Review**

**10558**, A Phase II Randomized Control Trial of Triapine Plus Lutetium Lu 177 Dotatate Versus Lutetium Lu 177 Dotatate Alone for Well-Differentiated Somatostatin Receptor-Positive Neuroendocrine Tumors (Version Date 11/08/22)

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**III Continuing Review**

**10222**, A Phase II study of olaparib and AZD6738 in isocitrate dehydrogenase (IDH) mutant solid tumors (Version Date 10/18/22)

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**IV Continuing Review**

**10330**, A Phase 2 Study of Belinostat and SGI-110 (Guadecitabine) or ASTX727 for the Treatment of Unresectable and Metastatic Conventional Chondrosarcoma (Version Date 06/15/22)

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**V Continuing Review**

**10445**, Phase I Dose Escalation and Expansion Study of Tazemetostat in Combination with Topotecan and Pembrolizumab in Recurrent Small Cell Lung Cancer (Version Date 08/08/22)

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## **VI Continuing Review**

**ABTC-1701**, Pilot Surgical PK Study of Bemcentinib in Recurrent Glioblastoma Patients (Version Date 10/07/21)

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## **VII Continuing Review**

**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 08/31/22)

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## **VIII Continuing Review**

**10218**, A Phase 1b Trial of Telaglenastat (CB-839) HCl in Combination with Radiation Therapy and Temozolomide in Patients with IDH-mutated Diffuse Astrocytoma and Anaplastic Astrocytoma (Version Date 10/12/21)

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