

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

**June 18, 2024**

---

**I New Study - Initial Review**

**10620**, A Phase 1b Trial of Teclistamab in Combination with Iberdomide for Relapsed/Refractory Multiple Myeloma (Version Date 05/14/24)

---

**II New Study - Initial Review**

**10630**, Phase 1 Trial of Iadademstat in Combination with Venetoclax and Azacitidine in Patients with Treatment Naive AML (Version Date 05/07/24)

---

**III Continuing Review**

**10042**, A Phase II trial of Osimertinib (AZD9291) with or without bevacizumab in patients with EGFR mutation positive NSCLC and brain metastases (Version Date 03/27/23)

---

**IV Continuing Review**

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

---

**V Continuing Review**

**9673**, PART A: A Multi-Institutional Phase 2 Study of Nivolumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal PART B: A Multi-Institutional Phase 2 Study of Nivolumab or Nivolumab in Combination with Ipilimumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal (Version Date 03/24/23)

---

## **VI Continuing Review**

**10221**, A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in patients with advanced solid tumors (Version Date 08/09/23)

---

## **VII Continuing Review**

**10371**, A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response (Version Date 12/29/23)

---

## **VIII Continuing Review**

**10285**, Phase 1/2 Study of an EZH2 inhibitor (tazemetostat) in combination with dual BRAF/MEK inhibition in patients with BRAF-mutated metastatic melanoma who progressed on prior BRAF/MEK inhibitor therapy (Version Date 03/04/24)

---

## **IX Continuing Review**

**10355**, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Version Date 07/18/23)

---