

Adult CIRB - Early Phase Emphasis Meeting Agenda

October 7, 2025

I Amendment

10507, A Phase 1/2 Study of the Bromodomain Inhibitor ZEN003694 in Combination with Etoposide/Platinum in Patients with NUT Carcinoma (Version Date 08/06/25)

II Continuing Review

9466, Phase I/II study of dabrafenib, trametinib, and navitoclax in BRAF mutant melanoma (Phase I and II) and other solid tumors (Phase I only) (Version Date 04/01/25)

III Continuing Review

9898, A Phase I Trial of Osimertinib (AZD9291) and Necitumumab in EGFR-Mutant Non-Small Cell Lung Cancer After Progression on a Previous EGFR Tyrosine Kinase Inhibitor (Version Date 08/20/24)

IV Continuing Review

10096, A Phase 1/2 Study of Combination Olaparib and Radium-223 in Men with Metastatic Castration-Resistant Prostate Cancer with Bone Metastases (COMRADE) (Version Date 12/18/24)

V Continuing Review

10292, DURVA+: Evaluation of the Safety and Pharmacodynamics of Anti-PD-L1 Antibody Durvalumab in Combination with Chemotherapy in Patients with Advanced Solid Tumors (Version Date 08/04/25)

VI 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 05/28/25)

VII Continuing Review

10512, A Phase 2 Randomized Study of the BER Inhibitor TRC102 in Combination with Standard Pemetrexed-Platinum-Radiation in Stage III Non-Squamous Non-Small Cell Lung Cancer (Version Date 07/07/25)

VIII Continuing Review

10522, A Phase 1 Clinical Trial of CA-4948 in Combination with Gemcitabine and Nab-Paclitaxel in Metastatic or Unresectable Pancreatic Ductal Carcinoma (Version Date 05/27/25)

IX Continuing Review

10674, A Phase I Study Evaluating the Safety of Cirtuvivint as Monotherapy and in Combination with ASTX727 in Patients with Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) (Version Date 06/26/25)
