

Adult CIRB - Early Phase Emphasis Meeting Agenda

August 1, 2023

I 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)

II 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 05/04/23)

III 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 01/10/23)

IV Continuing Review

10355, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Version Date 04/11/23)

V 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 05/18/23)