

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 2, 2025

I Continuing Review

10146, Randomized phase 2 clinical trial of nab-paclitaxel + durvalumab (MEDI4736) + tremelimumab + neoantigen vaccine vs. nab-paclitaxel + durvalumab (MEDI4736) + tremelimumab in patients with metastatic triple negative breast cancer (Version Date 12/16/24)

II Continuing Review

10449, A Phase 1 Study of ZEN003694 in Combination with Binimetinib in Solid Tumors with RAS Pathway Alterations and Triple Negative Breast Cancer (Version Date 10/17/25)

III Continuing Review

10499, Phase Ib/II Study of ZEN003694 and Entinostat in Advanced and Refractory Solid Tumors (Version Date 10/20/25)

IV Continuing Review

EA5162, Phase II Study of Osimertinib (AZD9291) in Advanced NSCLC Patients with Exon 20 Insertion Mutations in EGFR (Version Date 10/03/24)

V Amendment

10695, Phase 1 Study of Lintuzumab-Ac225 Monotherapy for Patients with Hypomethylating Agent-Refractory Myelodysplastic Syndrome (Version Date 10/10/25)
