

Adult CIRB - Early Phase Emphasis Meeting Agenda

August 6, 2024

I New Study - Initial Review

10647, Phase I/Ib Study of Eribulin in Combination with ASTX660 (tolinapant) in Metastatic Triple Negative Breast Cancer (TNBC) (Version Date 06/18/24)

II New Study - Initial Review

10657, Phase I/II Study to Evaluate the Feasibility and Efficacy of Sequential Abemaciclib and Gemcitabine Treatment in Patients with Retinoblastoma (Rb)+ Sarcomas (Version Date 06/12/24)

III Amendment

10597, A Phase 1 Study of APG-1252 (pelcitoclax) and cobimetinib in recurrent ovarian and endometrial cancers (Version Date 07/02/24)

IV Amendment

10273, A Phase 1 Study of M3814 in combination with MEC in Patients with Relapsed or Refractory Acute Myeloid Leukemia (Version Date 07/08/24)

V 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 08/01/23)

VI Continuing Review

10129, A Phase 2 Study of the PARP Inhibitor Olaparib (AZD2281) in IDH1 and IDH2 mutant Advanced Solid Tumors (Version Date 07/20/23)

VII Continuing Review

10335, A Phase 1 Study of Lenalidomide in Combination with EPOCH Chemotherapy for HTLV-Associated Adult T-Cell Leukemia-Lymphoma (ATLL) (Version Date 08/03/23)

VIII Continuing Review

10422, A Phase 1/1b Dose Escalation Study of Abemaciclib and Olaparib for Recurrent Platinum-Resistant Ovarian Cancer (Version Date 02/01/24)

IX Continuing Review

10403, Phase 1 Trial of Gemcitabine Combined with the Elimusertib (BAY 1895344) ATR Inhibitor with Expansion Cohorts in Advanced Pancreatic and Ovarian Cancer (Version Date 02/26/24)

X Continuing Review

EAY191, Molecular Analysis for Combination Therapy Choice (ComboMATCH) (Version Date 02/28/24)

XI Continuing Review

10204, A Phase 1b Study of Nivolumab in Patients with Autoimmune Disorders and Advanced Malignancies (AIM-NIVO) (Version Date 08/31/23)
