

Adult CIRB - Early Phase Emphasis Meeting Agenda

September 15, 2026

I Continuing Review

10572, A Phase 1/2 Trial Evaluating the Combination of Temozolomide and the Ataxia Telangiectasia and Rad3-related Inhibitor M1774 (Version Date 03/26/26)

II Continuing Review

10577, Pilot Study of CBX-12 Pharmacodynamics in Patients with Advanced Solid Tumors (Version Date 07/18/25)

III Continuing Review

10636, Phase 1 Trial of CA-4948 in Combination with Pembrolizumab to Overcome Resistance to PD-1/PD-L1 Blockade in Metastatic Urothelial Cancer (Version Date 08/08/26)

IV Continuing Review

EAY191-N5, A Randomized Trial of Neratinib, A Pan-ERBB Inhibitor, Alone or in Combination with Palbociclib, a CDK4/6 Inhibitor, in Patients with HER2+ Gynecologic Cancers and Other Solid Tumors: A ComboMATCH Treatment Trial (Version Date 02/18/26)

V Continuing Review

10546, Phase I Study Targeting DNA Methyltransferases in Metastatic Triple-Negative Breast Cancer (Version Date 08/13/25)

VI Continuing Review

10670, A Phase 1 Study of 5-Fluorouracil in Combination with Abemaciclib in Metastatic, Refractory CRC (Version Date 02/05/26)

VII Continuing Review

10553, A Phase 2 Study of Darolutamide in Combination with Leuprolide Acetate in Hormone-Therapy Naïve Recurrent and/or Metastatic Androgen Receptor (AR) Positive Salivary Gland Cancer (Version Date 08/06/25)
