

Adult CIRB - Early Phase Emphasis Meeting Agenda

October 21, 2025

I Amendment

10204, A Phase 1b Study of Nivolumab in Patients with Autoimmune Disorders and Advanced Malignancies (AIM-NIVO) (Version Date 08/07/25)

II Continuing Review

10572, A Phase 1/2 Trial Evaluating the Combination of Temozolomide and the Ataxia Telangiectasia and Rad3-related Inhibitor M1774 (Version Date 09/18/24)

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 04/07/25)

IV Continuing Review

10670, A Phase 1 Study of 5-Fluorouracil in Combination with Abemaciclib in Metastatic, Refractory CRC (Version Date 08/27/25)

V Continuing Review

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

VI 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)

VII Continuing Review

10558, A Phase II Randomized Control Trial of Triapine Plus Lutetium Lu 177 Dotatate Versus Lutetium Lu 177 Dotatate Alone for Well-Differentiated Somatostatin Receptor-Positive Neuroendocrine Tumors (Version Date 05/29/25)

VIII 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 10/22/24)
