

Adult CIRB - Early Phase Emphasis Meeting Agenda

May 19, 2026

I Amendment

10563, A Phase 1 Study of Peposertib (M3814) and Low-Dose Liposomal Doxorubicin in Patients with Metastatic Leiomyosarcoma and Other Soft Tissue Sarcomas (Version Date 04/17/26)

II Amendment

10411, Phase 2 Study of Rogaratinib (BAY 1163877) in the Treatment of Patients with Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-deficient Gastrointestinal Stromal Tumor (GIST) (Version Date 04/16/26)

III Amendment

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 04/14/26)

IV 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 12/17/24)

V Continuing Review

10422, A Phase 1/1b Dose Escalation Study of Abemaciclib and Olaparib for Recurrent Platinum-Resistant Ovarian Cancer (Version Date 02/13/26)

VI Continuing Review

10630, Phase 1 Trial of Iadademstat in Combination with Venetoclax and Azacitidine in Patients with Treatment Naive AML (Version Date 02/13/26)

VII Continuing Review

EAY191, Molecular Analysis for Combination Therapy Choice (ComboMATCH) (Version Date 11/14/25)

VIII Continuing Review

10204, A Phase 1b Study of Nivolumab in Patients with Autoimmune Disorders and Advanced Malignancies (AIM-NIVO) (Version Date 01/14/26)
