

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 16, 2024

I New Study - Initial Review

10674, A Phase I Study Evaluating the Safety of Cirtuvivint as Monotherapy and in Combination with ASTX727 and ASTX727 + Venetoclax in Patients with Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) (Version Date 06/04/24)

II 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 06/11/24)

III Continuing Review

EAY191-N4, Molecular Analysis for Combination Therapy Choice (ComboMATCH) EAY191-N4: A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers A ComboMATCH Treatment Trial (Version Date 03/27/24)

IV Continuing Review

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 07/26/23)

V Continuing Review

A051901, Phase I Trial of Methotrexate, Rituximab, Lenalidomide, and Nivolumab (NIVO-MR2) Induction Followed by Lenalidomide and Nivolumab Maintenance in Primary CNS Lymphoma (Version Date 04/12/24)
