

Adult CIRB - Early Phase Emphasis Meeting Agenda

June 17, 2025

I New Study - Initial Review

10660, A Phase I/II Study Evaluating the Safety, Tolerability, and Efficacy of Sotorasib Plus Trastuzumab Deruxtecan in Patients with Advanced Non-Small Cell Lung Cancer with a KRASG12C Mutation (Version Date 04/17/25)

II New Study - Initial Review

10702, A Phase II Study of Glofitamab for Relapsed/Refractory Mantle Cell Lymphoma in Patients Previously Treated with CD19-directed CAR T-cell Therapy (Version Date 04/30/25)

III 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 04/04/25)

IV 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 05/13/25)

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 03/21/25)