

Adult CIRB - Early Phase Emphasis Meeting Agenda

May 20, 2025

I New Study - Initial Review

10664, A Phase 1b Study of Combination Tovorafenib (DAY101) and Rituximab Treatment in Relapsed or Refractory Classical Hairy Cell Leukemia and Phase 2 Randomized Study Comparing Tovorafenib (DAY101) and Rituximab with Cladribine and Rituximab for Front-line Treatment of Classical Hairy Cell Leukemia (Version Date 04/03/25)

II Amendment

10637, A Phase 2 Study of Venetoclax in Relapsed Classic or Variant Hairy Cell Leukemia (Version Date 04/15/25)

III Amendment Prior to Activation

10653, A Phase I Study of Lintuzumab-Ac225 in Combination with Venetoclax and ASTX-727 in Adults with Newly Diagnosed AML (Version Date 04/02/25)

IV Continuing Review

10285, Phase 1/2 Study of an EZH2 inhibitor (tazemetostat) in combination with dual BRAF/MEK inhibition in patients with BRAF-mutated metastatic melanoma who progressed on prior BRAF/MEK inhibitor therapy (Version Date 03/21/25)

V Continuing Review

10371, A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response (Version Date 10/24/24)

VI Continuing Review

10221, A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in patients with advanced solid tumors (Version Date 10/24/24)
