

Adult CIRB - Early Phase Emphasis Meeting Agenda

February 21, 2023

I New Study - Initial Review

10561, Rapid Analysis and Response Evaluation of Combination Anti-neoplastic Agents in Rare Tumors (RARE CANCER) Trial: RARE 3 Tiragolumab + Atezolizumab (Version Date 12/27/22)

II New Study - Initial Review

10563, A Phase 1 Study of Peposertib (M3814) and Low-Dose Liposomal Doxorubicin (Doxil®) in Patients with Metastatic Leiomyosarcoma and Other Soft Tissue Sarcomas (Version Date 01/04/23)

III Continuing Review

10417, Clinical Evaluation of ASTX727 in Combination with Venetoclax All-Oral Therapy vs. Standard of Care Cytarabine and Anthracycline Induction Chemotherapy for Younger FLT3WT Patients with ELN High-Risk Acute Myeloid Leukemia (Version Date 11/15/22)

IV Continuing Review

10492, Phase 1/1b Study of AKT Inhibitor Ipatasertib with Chemoradiation for Locally Advanced Head and Neck Cancer (Version Date 09/07/22)

V Continuing Review

10499, Phase Ib/II study of ZEN003694 and entinostat in advanced and refractory solid tumors and lymphomas (Version Date 05/03/22)

VI Continuing Review

CITN-14, A Randomized Phase II Study of Atezolizumab (MPDL3280A) plus Recombinant Human IL-7 (CYT107) in patients with locally advanced or metastatic urothelial carcinoma (Version Date 10/12/22)

VII Continuing Review

10273, A Phase 1 Study of M3814 in combination with MEC in Patients with Relapsed or Refractory Acute Myeloid Leukemia (Version Date 11/01/21)
