

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 3, 2024

I New Study - Initial Review

10655, Phase I Clinical Trial of CA-4948 (emavusertib) in Combination with FOLFOX Plus Bevacizumab as Frontline Treatment in Patients with Metastatic Colorectal Cancer (Version Date 10/15/24)

II Amendment

10508, A Phase 1 Study of Nivolumab in Combination with ASTX727 in B-cell lymphoma (NHL or HL) with an Expansion Cohort in Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL) and Hodgkin lymphoma (HL) (Version Date 10/07/24)

III Continuing Review

10504, A Randomized Phase 2 Study of Atezolizumab with or without Selinexor in Alveolar Soft Part Sarcoma (AXIOM) (Version Date 09/29/23)

IV Continuing Review

10527, A Molecularly Driven Phase 1b Dose Escalation and Dose Expansion Study of the DNA-PK Inhibitor Peposertib (M3814) in Combination with the ATR Inhibitor Tuvusertib (M1774) (Version Date 11/01/24)

V Continuing Review

10577, Pilot Study of CBX-12 Pharmacodynamics in Patients with Advanced Solid Tumors (Version Date 10/11/24)

VI Continuing Review

NRG-HN008, Phase I Trial with Expansion Cohort of DNA-PK Inhibition and IMRT in Cisplatin-Ineligible Patients with Stage 3-4 Local-Regionally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) (Version Date 08/05/24)

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 07/08/24)

VIII Continuing Review

10434, Randomized Phase 2 Study of daunorubicin and cytarabine liposome + Pomalidomide versus daunorubicin and cytarabine liposome in Newly Diagnosed AML with MDS-Related Changes (Version Date 06/13/24)
