

Adult CIRB - Early Phase Emphasis Meeting Agenda

March 1, 2022

I Continuing Review

10329, Phase I Sequential Trial of Agents Against DNA Repair (STAR) (Protocol Version Date 09/28/21)

II Continuing Review

10382, A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination with Copanlisib in Patients with Metastatic Triple Negative Breast Cancer (Protocol Version Date 03/12/21)

III Continuing Review

9466, Phase I/II study of dabrafenib, trametinib, and navitoclax in BRAF mutant melanoma (Phase I and II) and other solid tumors (Phase I only) (Protocol Version Date 01/07/22)

IV Continuing Review

9706, Randomized phase II study to assess the role of Nivolumab as single agent to eliminate minimal residual disease and maintain remission in acute myelogenous leukemia (AML) patients after chemotherapy (REMAIN Trial) (Protocol Version Date 03/12/21)

V Continuing Review

9898, A Phase I Trial of AZD9291 and Necitumumab in EGFR-Mutant Non-Small Cell Lung Cancer After Progression on a Previous EGFR Tyrosine Kinase Inhibitor (Protocol Version Date 12/07/20)

VI Continuing Review

S1320, A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma (Protocol Version Date 06/18/20)

VII Amendment

10183, A Pilot Study of Tazemetostat and Pembrolizumab (MK-3475) in Advanced Urothelial Carcinoma (Protocol Version Date 01/04/22)
