

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 19, 2023

I Amendment

10507, A Phase 1/2 Study of the Bromodomain Inhibitor ZEN003694 in Combination with Etoposide/Platinum in Patients with NUT Carcinoma (Version Date 11/02/23)

II Amendment

10509, A Phase 1 Study of BET Bromodomain Inhibitor ZEN003694 in Combination with the CDK4/6 Inhibitor Abemaciclib in Patients with NUT Carcinoma and Other Solid Tumors (Version Date 11/03/23)

III 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 02/14/23)

IV 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) (Version Date 03/15/23)

V 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 (Version Date 07/22/22)

VI Continuing Review

10512, A Phase 2 Randomized Study of the BER Inhibitor TRC102 in Combination with Standard Pemetrexed-Platinum-Radiation in Stage III Non-Squamous Non-Small Cell Lung Cancer (Version Date 02/09/23)

VII Continuing Review

10558, A Phase II Randomized Control Trial of Triapine Plus Lutetium Lu 177 Dotatate Versus Lutetium Lu 177 Dotatate Alone for Well-Differentiated Somatostatin Receptor-Positive Neuroendocrine Tumors (Version Date 08/18/23)

VIII 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 (Version Date 04/26/23)

IX Continuing Review

10402, BAY 1895344 Plus Topoisomerase-1 (Top1) Inhibitors in Patients with Advanced Solid Tumors, Phase I Studies with Expansion Cohorts in Small Cell Lung Carcinoma (SCLC), Poorly Differentiated Neuroendocrine Carcinoma (PD-NEC) and Pancreatic Adenocarcinoma (PDA) (Version Date 01/03/23)

X Continuing Review

10553, A Phase 2 Study of Darolutamide in Combination with Leuprolide Acetate in Hormone-Therapy Naïve Recurrent and/or Metastatic Androgen Receptor (AR) Positive Salivary Gland Cancer (Version Date 07/25/23)

XI Continuing Review

10546, Phase I Study Targeting DNA Methyltransferases in Metastatic Triple-Negative Breast Cancer (Version Date 11/02/23)
