

Adult CIRB - Early Phase Emphasis Meeting Agenda

November 19, 2024

I New Study - Initial Review

10675, A Randomized Phase 2 Trial of ASTX727 +/- Iadademstat in Accelerated/Blast-Phase Philadelphia Chromosome-Negative Myeloproliferative Neoplasms (MPNs) (Version Date 09/18/24)

II Continuing Review

10445, Phase I Dose Escalation and Expansion Study of Tazemetostat in Combination with Topotecan and Pembrolizumab in Recurrent Small Cell Lung Cancer (Version Date 02/10/23)

III Continuing Review

EAY191-N5, A Randomized Trial of Neratinib, A Pan-ERBB Inhibitor, Alone or in Combination with Palbociclib, a CDK4/6 Inhibitor, in Patients with HER2+ Gynecologic Cancers and Other Solid Tumors: A ComboMATCH Treatment Trial (Version Date 10/22/24)

IV Amendment

10216, A Phase Ib Study of Osimertinib (AZD9291) and Telaglenastat (CB-839) HCl in Patients with EGFR Mutant Non-Small Cell Lung Cancer (Version Date 09/17/24)

V 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 03/08/24)

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 06/25/24)

VII Continuing Review

10572, A Phase 1/2 Trial Evaluating the Combination of Temozolomide and the Ataxia Telangiectasia and Rad3-related Inhibitor M1774 (Version Date 09/18/24)

VIII 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 03/19/24)

IX Continuing Review

10522, A Phase 1 Clinical Trial of CA-4948 in Combination with Gemcitabine and Nab-Paclitaxel in Metastatic or Unresectable Pancreatic Ductal Carcinoma (Version Date 09/09/24)

X Continuing Review

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

XI 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 05/28/24)

XII 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 09/12/24)
