

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 18, 2023

I New Study - Initial Review

10592, A Randomized Phase 2 Study of ATR inhibition in advanced PD-(L)1-refractory Merkel cell carcinoma: The MATRiX Trial (Version Date 06/06/23)

II Amendment

10327, A Phase 1 Trial of MLN0128 (sapanisertib) and Telaglenastat (CB-839) HCl in Advanced NSCLC Patients (Version Date 06/05/23)

III Continuing Review

10505, A Phase 1 and Randomized Phase 2 Trial of Selinexor and Temozolomide in Recurrent Glioblastoma (Version Date 10/17/22)

IV Continuing Review

NRG-LU004, Phase I Trial of Radiotherapy Combined With Durvalumab Alone Plus Either Monalizumab or Oleclumab in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1) (Version Date 06/12/23)

V Continuing Review

10517, An Open Label, Randomized Phase II Study Neoadjuvant Erdafitinib with or without Atezolizumab in Cisplatin-Ineligible Patients with Muscle Invasive Bladder Cancer (NERA) (Version Date 04/17/23)

VI Continuing Review

10483, Phase Ib trial of Erdafitinib combined with Enfortumab Vedotin following platinum and PD1/L1 inhibitors for metastatic urothelial carcinoma with FGFR2/3 genetic alterations (Version Date 04/11/23)

VII 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)

VIII Continuing Review

10056, A Phase 2 Study of Talimogene Laherparepvec (T-VEC) and Radiation in Localized Soft Tissue Sarcoma (Version Date 03/02/23)
