

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 15, 2024

I New Study - Initial Review

CTIU2317-A082304-S2402, Perioperative versus Adjuvant Systemic Therapy in Patients with Resectable Non-Small Cell Lung Cancer - PROSPECT LUNG (Version Date 07/12/24)

II New Study - Initial Review

S1800E, A Randomized Phase II/III Study of Docetaxel and Ramucirumab with or without Cemiplimab (REGN2810) for Participants Previously Treated with Platinum-Based Chemotherapy and Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study) (Version Date 07/15/24)

III Continuing Review

S1914, A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC (Version Date 02/23/24)

IV Continuing Review

S2012, Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC #783608) in Patients with Advanced or Metastatic Poorly Differentiated Extrapulmonary Neuroendocrine Carcinomas (NEC) (Version Date 01/23/24)

V Continuing Review

EA8171, Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for Newly-Diagnosed Prostate Cancer (Version Date 06/07/23)



VI Continuing Review

EA8192, A Phase II/III trial of Durvalumab and Chemotherapy for Patients with High Grade Upper Tract Urothelial Cancer Prior to Nephroureterectomy (Version Date 05/17/24)

VII Continuing Review

NRG-GY020, A Phase III Randomized Trial of Radiation +/- Pembrolizumab (MK-3475) for Newly Diagnosed Early Stage High Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid Endometrial Cancer (Version Date 05/09/23)

VIII Continuing Review

A032103, MODERN: An Integrated Phase 2/3 and Phase 3 Trial of MRD-Based Optimization of ADjuvant ThErapy in URothelial CaNcer (Version Date 07/16/24)