

Adult CIRB - Late Phase Emphasis Meeting Agenda

January 16, 2025

I New Study - Initial Review

NRG-GU014, Randomized Phase II Trial of Pembrolizumab and Radiation vs. Radiation and Concurrent Chemotherapy for High-Grade T1 Bladder Cancer (PARRC Trial) (Version Date 12/24/24)

II New Study - Initial Review

A012303, ShortStop-HER2: Shortened Duration of Adjuvant Therapy in Patients with Early-Stage HER2+ Breast Cancer Who Achieve pCR After Neoadjuvant Chemotherapy with HER2 Blockade (Version Date 12/11/24)

III Continuing Review

10272, A Phase II Multi-Institutional Trial to Evaluate Prostate Specific Membrane Antigen (PSMA)-Based PET Imaging of High Risk Prostate Cancer (Version Date 09/10/24)

IV Continuing Review

A021602, Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo in Patients with Advanced Neuroendocrine Tumors After Progression on Prior Therapy (CABINET) (Version Date 10/21/24)

V Continuing Review

A021804, A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma (Version Date 10/24/24)

VI Continuing Review

EA2174, A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma (Version Date 08/15/23)

VII Continuing Review

EA7211, A Randomized Phase III Study of Neoadjuvant Chemotherapy followed by Surgery versus Surgery Alone for Patients with High Risk RetroPeritoneal Sarcoma (STRASS 2) (Version Date 08/08/24)

VIII Memos

EA7211, A Randomized Phase III Study of Neoadjuvant Chemotherapy followed by Surgery versus Surgery Alone for Patients with High Risk RetroPeritoneal Sarcoma (STRASS 2) (Version Date 08/08/24)

IX Continuing Review

EAA173, Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) (Version Date 07/25/23)

X Continuing Review

N0577, N0577 (CODEL): Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma (Version Date 04/10/23)

XI Continuing Review

NRG-GU002, Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation following Radical Prostatectomy with or without Adjuvant Docetaxel (Version Date 08/26/19)

XII Continuing Review

NRG-GU012, Randomized Phase II Stereotactic Ablative Radiation Therapy (SABR) for Metastatic Unresected Renal Cell Carcinoma (RCC) Receiving Immunotherapy (SAMURAI) (Version Date 10/29/24)

XIII Continuing Review

S2005, A Phase II Randomized Study Comparing Ibrutinib and Rituximab vs. Venetoclax and Rituximab in Previously Untreated Waldenström's Macroglobulinemia (WM) /Lymphoplasmacytic Lymphoma (LPL) (Version Date 10/27/23)

XIV Continuing Review

S2107, Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab (NSC #748726) for Patients with Previously Treated, Microsatellite Stable, BRAFV600E Metastatic and/or Unresectable Colorectal Cancer (Version Date 08/10/23)

XV Continuing Review

S2303, Randomized Phase II/III Trial of 2nd Line Nivolumab + Paclitaxel + Ramucirumab versus Paclitaxel + Ramucirumab in Patients with PD-L1 CPS \geq 1 Advanced Gastric and Esophageal Adenocarcinoma (PARAMUNE) (Version Date 07/29/24)
