

Adult CIRB - Late Phase Emphasis Meeting Agenda

July 17, 2025

I New Study - Initial Review

A072301, Phase III Trial of Radiotherapy Followed by Adjuvant Temozolomide in Combination with the IDH Inhibitor Vorasidenib vs Placebo in IDH-Mutated Newly-Diagnosed Grade 3 Astrocytomas (Version Date 05/29/25)

II New Study - Initial Review

NRG-GY037, A Phase III Study of Induction Pembrolizumab and Chemotherapy Followed by Chemoradiation and Pembrolizumab vs Chemoradiation and Pembrolizumab Both Followed by Pembrolizumab or High Risk Locally Advanced Cervical Cancer (Version Date 06/18/25)

III New Study - Initial Review

S2427, Single Arm Phase II Study of Bladder Preservation with Immunoradiotherapy After a Clinically Meaningful Response to Neoadjuvant Therapy in Patients with Muscle Invasive Bladder Cancer (BRIGHT) (Version Date 06/16/25)

IV Amendment

CCTG-NE1, NET RETREAT: A Phase II Study of 177 Lutetium-DOTATATE Retreatment vs. Everolimus in Metastatic/Unresectable Midgut NET (Version Date 05/30/25)

V Amendment Prior to Activation

EA8231, A Phase III Randomized Trial of Pembrolizumab in Combination with Sacituzumab Govitecan vs Standard of Care in Anti-PD(L)1-Resistant Advanced Urothelial Cancer (Version Date 05/09/25)

VI 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 05/06/25)

VII Continuing Review

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

VIII 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 03/05/25)

IX Continuing Review

NRG-GY036, A Phase III Trial of One vs. Two Years of Maintenance Olaparib, with or without Bevacizumab, in Patients with BRCA1/2 Mutated or Homologous Recombination Deficient (HRD+) Ovarian Cancer Following Response to First Line Platinum-Based Chemotherapy (Version Date 12/31/24)

X Continuing Review

NRG-HN014, Randomized Phase III Trial of Neoadjuvant Immunotherapy with Response Adapted Treatment versus Standard of Care Treatment for Resectable Stage III/IV Cutaneous Squamous Cell Carcinoma (Version Date 09/23/24)

XI 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 03/13/25)