

Adult CIRB - Late Phase Emphasis Meeting Agenda

September 7, 2023

I New Study - Initial Review

EA3222, Phase II Trial of Xevinapant and Chemoradiotherapy in Adjuvant Treatment for Patients with Head and Neck Squamous Cell Carcinoma with High Risk Pathologic Features (Version Date 08/11/23)

II New Study - Initial Review

NRG-GY033, A Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Combination with Leuprolide Acetate and Exemestane in Recurrent Adult-Type Ovarian Granulosa Cell Tumor (Version Date 07/27/23)

III New Study - Initial Review

NRG-HN011, A Randomized Phase II Study of Nivolumab Versus Nivolumab and BMS-986016 (Relatlimab) as Maintenance Treatment After First-Line Treatment with Platinum-Gemcitabine-Nivolumab for Patients with Epstein-Barr Virus-Associated Recurrent/Metastatic Nasopharyngeal Carcinoma (REMAIN) (Version Date 08/02/23)

IV Amendment

A032002, Phase II Randomized Trial of Atezolizumab versus Atezolizumab and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (ART) (Version Date 08/04/23)

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 12/02/22)

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

NRG-LU006, Phase III Randomized Trial of Pleurectomy/Decortication Plus Systemic Therapy with or without Adjuvant Hemithoracic Intensity-Modulated Pleural Radiation Therapy (IMPRINT) for Malignant Pleural Mesothelioma (MPM) (Version Date 04/13/22)

IX 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 11/02/22)

X Continuing Review

S2012, Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC #783608) in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC) (Version Date 11/04/22)

XI Continuing Review

S1416, Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer with or Without Brain Metastases (Version Date 10/05/21)
