

Adult CIRB - Late Phase Emphasis Meeting Agenda

December 15, 2022

I New Study - Initial Review

EA1211, Interim FDG-PET/CT for PreDIcting REsponse of HER2+ Breast Cancer to Neoadjuvant Therapy: DIRECT trial (Version Date 11/11/22)

II New Study - Initial Review

EA3211, Phase III Randomized Trial of Immunotherapy with or without Consolidative Radiotherapy for Oligometastatic Head and Neck Squamous Cell Carcinoma (Version Date 11/22/22)

III Amendment

S1608, Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma (Version Date 10/06/22)

IV Continuing Review

ABTC-1802, A Phase II Study of Binimetinib in Combination with Encorafenib in Adults with Recurrent BRAF V600-Mutated High-Grade Astrocytoma or other Primary Brain Tumor (Version Date 05/24/21)

V Continuing Review

A031704, PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE] (Version Date 08/16/22)

VI Continuing Review

EA6194, Phase II Randomized Study of Neoadjuvant Pembrolizumab Alone or in Combination with CMP-001 in Patients with Operable Melanoma: Efficacy and Biomarker Study (Version Date 09/23/22)

VII Continuing Review

EA8143, A Phase 3 RandOmized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC) (Version Date 09/16/21)

VIII Continuing Review

EAF151, Change in Relative Cerebral Blood Volume as a Biomarker for Early Response to Bevacizumab in Patients with Recurrent Glioblastoma (Version Date 03/09/21)

IX Continuing Review

NRG-BN010, A Safety Run-In and Phase II Study Evaluating the Efficacy, Safety, and Impact on the Tumor Microenvironment of the Combination of Tocilizumab, Atezolizumab, and Fractionated Stereotactic Radiotherapy in Recurrent Glioblastoma (Version Date 11/14/22)

X Continuing Review

NRG-BR002, A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer (Version Date 09/21/22)

XI Continuing Review

NRG-GY023, A Randomized Phase II Trial of Triplet Therapy (A PD-L1 Inhibitor Durvalumab (MEDI4736) in Combination with Olaparib and Cediranib) Compared to Olaparib and Cediranib or Durvalumab (MEDI4736) and Cediranib

or Standard of Care Chemotherapy in Women with Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer who have Received Prior Bevacizumab (Version Date 08/23/22)

XII Continuing Review

S2015, Melanoma Margins Trial (MelMarT): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma (Version Date 12/22/21)

XIII Continuing Review

EA2201, A Phase II Study of Neoadjuvant Nivolumab plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma (Version Date 09/03/21)
