

Adult CIRB - Late Phase Emphasis Meeting Agenda

July 1, 2021

I Continuing Review

ABTC-1804, Determining the Dose of Regadenoson Most Likely to Transiently Alter the Integrity of the Blood-Brain Barrier in Patients with Gliomas (Protocol Version Date 07/27/20)

II Continuing Review

E1A11, Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE) (Protocol Version Date 10/21/20)

III Continuing Review

EA2176, A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients (Protocol Version Date 02/01/21)

IV Continuing Review

EA2186, A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT) (Protocol Version Date 10/05/20)

V Continuing Review

EA3132, Phase II Randomized Trial of Radiotherapy with or without Cisplatin for Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN) with TP53 Sequencing (Protocol Version Date 03/10/20)

VI Continuing Review

EA4151, A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma in Minimal Residual Disease-Negative First Complete Remission (Protocol Version Date 05/07/20)

VII Continuing Review

EA6141, Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma (Protocol Version Date 04/13/21)

VIII Continuing Review

NRG-BR003, A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer (Protocol Version Date 07/01/19)

IX Continuing Review

NRG-GU009, Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (PREDICT-RT) (Protocol Version Date 10/29/20)

X Continuing Review

NRG-HN004, Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Locoregionally Advanced Head and Neck Cancer with a Contraindication to Cisplatin (Protocol Version Date 01/13/21)

XI Continuing Review

RTOG-1216, Randomized Phase II/III Trial of Adjuvant Radiation Therapy with Cisplatin, Docetaxel-Cetuximab, or Cisplatin-Atezolizumab in Pathologic High-Risk, Squamous Cell Cancer of the Head and Neck (Protocol Version Date 06/02/21)

XII Continuing Review

RTOG-1308, Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Chemoradiotherapy For Inoperable Stage II-IIIB NSCLC (Protocol Version Date 08/20/19)

XIII Continuing Review

S1827, MRI Brain Surveillance Alone versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK) (Protocol Version Date 05/04/21)

XIV New Study - Initial Review

A032002, Phase II Randomized Trial of Atezolizumab versus Atezolizumab and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (ART) (Protocol Version Date 05/18/21)

XV Amendment

A011202, A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy (Protocol Version Date 05/21/21)
