

Adult CIRB - Late Phase Emphasis Meeting Agenda

May 19, 2022

I 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)

II 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 04/04/22)

III 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 09/20/21)

IV 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 12/10/21)

V 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 08/13/21)

VI 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)

VII 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 09/24/21)

VIII Continuing Review

S2000, A Randomized Phase 2 Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Brain Metastases (Protocol Version Date 01/28/21)

IX Amendment

A031901, Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A Randomized Phase 3 Non-Inferiority Trial (IMAGINE) (Protocol Version Date 04/27/22)

X Amendment

EA8191, Phase III Study of Local or Systemic Therapy Intensification Directed by PET in Prostate Cancer Patients with Post-Prostatectomy Biochemical Recurrence (INDICATE) (Protocol Version Date 04/26/22)
