

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 6, 2020

I Continuing Review

10231, NCORP Tissue Procurement Protocol: An NCI Cancer Moonshot Study (Protocol Version Date 09/20/19)

II Continuing Review

A091401, Randomized Phase II Study Of Nivolumab With Or Without Ipilimumab In Patients With Metastatic Or Unresectable Sarcoma (Protocol Version Date 05/22/19)

III 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 07/01/20)

IV Continuing Review

CALGB-30610, Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin or Carboplatin and Etoposide (Protocol Version Date 08/02/18)

V 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 09/23/19)

VI Continuing Review

E2112, A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer (Protocol Version Date 05/22/19)

VII 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 05/07/20)

VIII 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)

IX 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)

X 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 06/16/20)

XI 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)

XI Continuing Review

NRG-GY022, Assessment of Carboplatin Clearance Predictors: A PK Study on NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Protocol Version Date 08/22/19)

XII 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 06/05/20)

XIII 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)

XIV Continuing Review

S1815, A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers (Protocol Version Date 04/15/20)

XV New Study - Initial Review

EA2197, Optimal Perioperative Therapy For Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial (Protocol Version Date 06/23/20)

XVI New Study - Initial 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 07/10/20)

XVII Amendment

A031702, A Phase II Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC) (Protocol Version Date 06/25/20)
