

Adult CIRB - Late Phase Emphasis Meeting Agenda

July 21, 2022

I Continuing Review

A031801, A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (RadiCaL) (Protocol Version Date 02/15/22)

II Continuing Review

A092001, Phase 2 Randomized Trial of Neoadjuvant or Palliative Chemotherapy with or Without Immunotherapy for Peritoneal Mesothelioma (Protocol Version Date 03/07/22)

III Continuing Review

EA1183, FDG PET to Assess Therapeutic Response in Patients with Bone-dominant Metastatic Breast Cancer, FEATURE (Protocol Version Date 09/03/21)

IV Continuing Review

EA2183, A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA) (Protocol Version Date 12/14/21)

V Continuing Review

EA3163, Phase II randomized trial of neoadjuvant chemotherapy followed by surgery and post-operative radiation versus surgery and post-operative radiation for organ preservation of T3 and T4a (and selected T4b) nasal and paranasal sinus squamous cell carcinoma (NPNSCC) (Protocol Version Date 10/19/21)

VI Continuing Review

EA9152, A Phase Ib/II Study of Venetoclax (ABT-199) in Combination with Liposomal Vincristine in Patients with Relapsed or Refractory T-cell or B-cell Acute Lymphoblastic Leukemia (Protocol Version Date 11/18/21)

VII Continuing Review

EA9181, A Phase III Randomized Trial of Steroids + Tyrosine Kinase Inhibitor (TKI) Induction with Chemotherapy or Blinatumomab for Newly Diagnosed BCR-ABL-positive Acute Lymphoblastic Leukemia (ALL) in Adults (Protocol Version Date 05/24/22)

VIII Continuing Review

NRG-LU002, Maintenance Systemic Therapy versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial (Protocol Version Date 10/25/21)

IX Continuing Review

S1701, A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma (Protocol Version Date 01/08/21)

X Continuing Review

S2104, Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors (Protocol Version Date 09/02/21)

XI New Study ReReview

ABTC-1604, Phase 0/I Study of AMG 232 (KRT 232) Concentrations in Brain Tissue in Patients with Recurrent Glioblastoma and of AMG 232 (KRT 232) in Combination with Radiation in Patients with Newly Diagnosed Glioblastoma and Unmethylated MGMT Promoters (Protocol Version Date 07/08/22)

XII New Study - Initial Review

AMC-115, Use of a Screening Tool to Describe HIV-Related Cancer Burden and Patient Characteristics in the AIDS Malignancy Consortium (Protocol Version Date 06/06/22)

XIII New Study - Initial Review

EA8212, A Randomized Phase III Trial of Intravesical BCG veRsus Intravesical Docetaxel and GEmcitabine Treatment in BCG Naïve High Grade Non-Muscle Invasive Bladder Cancer (BRIDGE) (Protocol Version Date 05/24/22)

XIV New Study - Initial Review

S2101, Biomarker Stratified CaboZantinib (NSC#761968) and NivOlumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Participants with Advanced Solid Tumors (IO Refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers - an immunoMATCH Pilot Study (Protocol Version Date 06/17/22)

XV Amendment

EA2174, A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma (Protocol Version Date 06/08/22)
