

Adult CIRB - Late Phase Emphasis Meeting Agenda

January 20, 2022

I 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 (Protocol Version Date 05/24/21)

II 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 (Protocol Version Date 10/21/21)

III Continuing Review

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

IV Continuing Review

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

V 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 (Protocol Version Date 08/12/21)

VI 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 (Protocol Version Date 08/27/21)

VII New Study - Initial Review

A022001, Phase II Randomized, Prospective Trial of Lutetium Lu 177 Dotatate PRRT Versus Capecitabine and Temozolomide in Well-Differentiated Pancreatic Neuroendocrine Tumors (Protocol Version Date 12/09/21)

VIII New Study - Initial Review

EA2205, A Randomized Phase II Trial Evaluating Chemotherapy vs Chemotherapy plus Bevacizumab and Atezolizumab in Advanced Combined Hepatocellular Carcinoma-Cholangiocarcinoma (Protocol Version Date 12/10/21)

IX Amendment

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)

X Amendment

EA9161, A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 01/05/22)

XI Memos

S1905, A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL) (Protocol Version Date)
