

Adult CIRB - Late Phase Emphasis Meeting Agenda

March 21, 2024

I New Study - Initial Review

A072201, Randomized Phase II Trial of Anti-Lag-3 and Anti-PD-1 Blockade vs. SOC in Patients with Recurrent Glioblastoma (Version Date 01/31/24)

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) (Version Date 04/04/22)

III Continuing Review

A082002, A Randomized Phase II/III Trial of Modern Immunotherapy Based Systemic Therapy with or without SBRT for PD-L1-Negative, Advanced Non-small Cell Lung Cancer (Version Date 11/21/23)

IV Continuing Review

EA8211, Phase III Randomized Trial of Stereotactic Ablative Radiotherapy (SAbR) for Oligometastatic Advanced Renal Carcinoma (SOAR) (Version Date 11/03/23)

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 (Version Date 08/22/23)

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 (Version Date 05/18/23)

VII Continuing Review

S2000, A Randomized Phase II Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Symptomatic Brain Metastases (Version Date 08/21/23)

VIII Continuing Review

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) (Version Date 02/01/23)

IX 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 (Version Date 02/12/24)

X Continuing Review

EA2176, A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients (Version Date 08/15/23)
