

Adult CIRB - Late Phase Emphasis Meeting Agenda

February 6, 2025

I Amendment

EA9213, A Phase II Study of Daratumumab-Hyaluronidase for Chemotherapy-Relapsed/Refractory Minimal Residual Disease (MRD) in T Cell Acute Lymphoblastic Leukemia (T-ALL) (Version Date 12/19/24)

II Amendment

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) (Version Date 10/28/24)

III 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 01/08/25)

IV 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 11/22/24)

V Continuing Review

A011801, The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer): CompassHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinb (Version Date 12/03/24)

VI Continuing Review

A091404, A Phase II Study of Enzalutamide (NSC# 766085) for Patients with Androgen Receptor Positive Salivary Cancers (Version Date 09/10/19)

VII Continuing Review

RTOG-1308, Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Chemoradiotherapy For Inoperable Stage II-III B NSCLC (Version Date 05/28/24)

VIII 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)

IX 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 (Version Date 07/23/24)

X 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 (Version Date 08/29/24)

XI Continuing Review

EA6174, STAMP: Surgically Treated Adjuvant Merkel cell Carcinoma with Pembrolizumab, a Phase III Trial (Version Date 10/30/24)

XII Continuing Review

S1922, Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI In Refractory Small Bowel Adenocarcinoma (Version Date 03/20/23)

XIII Continuing Review

EA2222, A Randomized Phase III Study of Systemic Therapy with or without Hepatic Arterial Infusion for Unresectable Colorectal Liver Metastases: The PUMP Trial (Version Date 11/27/24)

XIV 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) (Version Date 05/16/24)
