

Adult CIRB - Late Phase Emphasis Meeting Agenda

March 7, 2024

I New Study - Initial Review

MM10A-EA02, A Randomized Phase II Study of Venetoclax and HMA-Based Therapies for the Treatment of Older and Unfit Adults with Newly Diagnosed FLT3-Mutated Acute Myeloid Leukemia (AML): A MyeloMATCH Treatment Trial (Version Date 02/01/24)

II Amendment

A042001, A Randomized Phase II Study Comparing Inotuzumab Plus Chemotherapy versus Standard Chemotherapy in Older Adults with Philadelphia-Chromosome-Negative B-cell Acute Lymphoblastic Leukemia (Version Date 01/18/24)

III Amendment

EA2183, A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA) (Version Date 02/01/24)

IV 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 06/23/22)

V Continuing Review

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

VI Continuing Review

EA6174, STAMP: Surgically Treated Adjuvant Merkel cell Carcinoma with Pembrolizumab, a Phase III Trial (Version Date 10/16/23)

VII 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 (Version Date 07/01/19)

VIII 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 05/31/23)

IX Continuing Review

NRG-GY004, A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Version Date 07/27/23)

X Continuing Review

NRG-GY024, Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial (Version Date 10/19/23)

XI 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 01/11/24)

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 (Version Date 10/18/23)

XIII Continuing Review

RTOG-1308, Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Chemoradiotherapy For Inoperable Stage II-IIIB NSCLC (Version Date 10/06/21)

XIV Continuing Review

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

XV Continuing Review

EA8183, A Phase III Double Blinded Study of Early Intervention after RADICAL ProstaTEctomy with Androgen Deprivation Therapy with Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE) (Version Date 09/13/21)
