

Adult CIRB - Late Phase Emphasis Meeting Agenda

October 6, 2022

I New Study - Initial Review

A022104, The Janus Rectal Cancer Trial: A Randomized Phase II Trial Testing the Efficacy of Triplet versus Doublet Chemotherapy to Achieve Clinical Response in Patients with Locally Advanced Rectal Cancer (Version Date 09/02/22)

II New Study - Initial Review

MM1YA-CTG01, A Measurable Residual Disease (MRD) Driven, Phase II Study of Venetoclax plus Chemotherapy for Newly Diagnosed Younger Patients with Intermediate Risk Acute Myeloid Leukemia: A Tier 1 MyeloMATCH Clinical Trial (Version Date 08/17/22)

III New Study - Initial Review

MM2YA-EA01, Eradicating Measurable Residual Disease in Patients with Acute Myeloid Leukemia (AML) Prior to StEm Cell Transplantation (ERASE): A MyeloMATCH Treatment Trial (Version Date 08/19/22)

IV Continuing Review

EA8171, Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for Newly-Diagnosed Prostate Cancer (Version Date 08/15/22)

V Continuing Review

EA8192, A Phase II/III trial of MEDI4736 (Durvalumab) and Chemotherapy for Patients with High Grade Upper Tract Urothelial Cancer Prior to Nephroureterectomy (Version Date 01/21/21)

VI Continuing Review

EA9171, BLAST MRD CML 1 Trial: BLockade of PD-1 Added to Standard Therapy to Target Measurable Residual Disease (MRD) in Chronic Myeloid Leukemia (CML)- A Phase II Study of Adding the Anti-PD-1 Pembrolizumab to Tyrosine Kinase Inhibitors in Patients with CML and Persistently Detectable MRD (Version Date 04/08/22)

VII Continuing Review

NRG-GY020, A Phase III Randomized Trial of Radiation +/- Pembrolizumab (MK-3475) for Newly Diagnosed Early Stage High Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid Endometrial Cancer (Version Date 10/19/21)

VIII Continuing Review

NRG-LU006, Phase III Randomized Trial of Pleurectomy/Decortication Plus Systemic Therapy with or without Adjuvant Hemithoracic Intensity-Modulated Pleural Radiation Therapy (IMPRINT) for Malignant Pleural Mesothelioma (MPM) (Version Date 04/13/22)

IX Continuing Review

S1416, Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer with or Without Brain Metastases (Version Date 10/05/21)

X Continuing Review

S1914, A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC (Version Date 06/13/22)

XI Continuing Review

S2012, Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC #783608) in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC) (Version Date 10/27/21)
