

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 3, 2023

I New Study ReReview

S2213, A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis (Version Date 07/17/23)

II Amendment

AMC-112, Axicabtagene Ciloleucel in Relapsed or Refractory HIV-Associated Aggressive B-Cell Non-Hodgkin Lymphoma (Version Date 06/30/23)

III Amendment

EA3191, A Phase II Randomized Trial of Adjuvant Therapy with Pembrolizumab after Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma with High Risk Features (Version Date 06/16/23)

IV Continuing Review

A021703, Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS) (Version Date 09/20/22)

V Continuing Review

EA1131, A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Capecitabine in Patients with Residual Triple-Negative Breast Cancer following Neoadjuvant Chemotherapy (Version Date 12/09/22)

VI Continuing Review

EA1181, (CompassHER2-pCR): Preoperative THP and postoperative HP in patients who achieve a pathologic complete response (Version Date 05/10/23)

VII Continuing Review

NRG-BN003, Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma (Version Date 05/13/22)

VIII Continuing Review

NRG-GI004, Colorectal Cancer Metastatic dMMR/MSI-H Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab/Atezolizumab Combination versus Single Agent Atezolizumab in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR)/Microsatellite Instability-High (MSI-H) Metastatic Colorectal Cancer (Version Date 02/20/23)

IX Continuing Review

NRG-GY009, A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab (IND #134427) versus Pegylated Liposomal Doxorubicin, CTEP-Supplied Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin and CTEP-Supplied Bevacizumab in Platinum Resistant Ovarian Cancer (Version Date 10/13/22)
