

Adult CIRB - Late Phase Emphasis Meeting Agenda

September 15, 2022

I Continuing Review

A021703, Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS) (Protocol Version Date 10/08/20)

II Continuing Review

AMC-108, Multicenter Phase II Study of Pomalidomide Monotherapy in Kaposi Sarcoma (Protocol Version Date 08/05/22)

III 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 (Protocol Version Date 03/01/21)

IV Continuing Review

EA1181, (CompassHER2-pCR): Preoperative THP and postoperative HP in patients who achieve a pathologic complete response (Protocol Version Date 02/28/22)

VI Continuing Review

EA2187, A Phase 2 Study of Pevonedistat in Combination with Carboplatin and Paclitaxel in Advanced Intrahepatic Cholangiocarcinoma (Protocol Version Date 09/01/21)

VII Continuing Review

NRG-BN003, Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma (Protocol 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 (Protocol Version Date 06/07/21)

IX Continuing Review

NRG-GU011, A Phase II Double-Blinded, Placebo Controlled Trial of Prostate Oligometastatic Radiotherapy with or without Androgen Deprivation Therapy in Oligometastatic Prostate Cancer (NRG PROMETHEAN) (Protocol Version Date 03/15/22)

X New Study - Initial Review

MM1YA-S01, A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7+3) to (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax and Azacitidine + Venetoclax in Patients Aged 59 or Younger with High Risk (Adverse) Acute Myeloid Leukemia; A MyeloMATCH Clinical Trial (Protocol Version Date 08/08/22)

XI New Study - Initial Review

MyeloMATCH, Master Screening and Reassessment Protocol (MSRP) for the NCI MyeloMATCH Clinical Trials (Protocol Version Date 06/01/22)

XII Amendment

A021703, Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS) (Protocol Version Date 08/09/22)
