

Adult CIRB - Late Phase Emphasis Meeting Agenda

June 5, 2025

I New Study - Initial Review

EAA241, A Randomized Phase II Trial Comparing Daratumumab-Bortezomib-Dexamethasone versus Cyclophosphamide-Bortezomib-Dexamethasone in Newly Diagnosed Multiple Myeloma with Light Chain Cast Nephropathy (LCCN) (Version Date 04/11/25)

II 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)

III Continuing Review

EA1181, (CompassHER2-pCR): Preoperative THP and postoperative HP in patients who achieve a pathologic complete response (Version Date 10/16/24)

IV Continuing Review

NRG-BN003, Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma (Version Date 12/12/24)

V Continuing Review

NRG-BN014, A Phase III Randomized Clinical Trial of Proton Craniospinal Irradiation versus Involved-Field Radiotherapy for Patients with Breast Cancer or Non-Small Cell Lung Cancer Leptomeningeal Metastasis (RADIATE-LM) (Version Date 08/26/24)

VI 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 10/09/23)

VII 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) (Version Date 03/27/25)

VIII 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 03/10/25)

IX Continuing Review

S2312, A Phase III Study of Cabazitaxel with or without Carboplatin in Patients with Metastatic Castrate Resistant Prostate Cancer (MCRPC), Stratified by Aggressive Variant Signature (Version Date 06/25/24)

X Continuing Review

MM1YA-S01, A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7+3) vs (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax, Azacitidine + Venetoclax, and (Daunorubicin and Cytarabine) Liposome + Venetoclax in Patients Aged 59 or Younger Who Are Considered High-Risk (Adverse) Acute Myeloid Leukemia as Determined by myeloMATCH; A myeloMATCH Clinical Trial (Version Date 07/17/24)

XI 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)

XII 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 04/17/25)
