

**Adult CIRB - Late Phase Emphasis Meeting Agenda**

**July 18, 2024**

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**I New Study - Initial Review**

**A032102**, PREcision DIagnostics in Prostate Cancer Treatment (PREDICT) (Version Date 05/30/24)

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**II New Study ReReview**

**NRG-GY036**, A Phase III Trial of One vs. Two Years of Maintenance Olaparib, with or without Bevacizumab, in Patients with BRCA1/2 Mutated or Homologous Recombination Deficient (HRD+) Ovarian Cancer Following Response to First Line Platinum-Based Chemotherapy (Version Date 06/28/24)

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**III Amendment**

**NRG-HN006**, Randomized Phase II/III Trial of Sentinel Lymph Node Biopsy versus Elective Neck Dissection for Early-Stage Oral Cavity Cancer (Version Date 05/16/24)

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**IV Amendment**

**S1802**, Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer (Version Date 06/07/24)

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**V Continuing Review**

**S2206**, Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for Adults with MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive/Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer (Version Date 05/22/24)

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## **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)

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## **VII 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)

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## **VIII Continuing Review**

**EA1181**, (CompassHER2-pCR): Preoperative THP and postoperative HP in patients who achieve a pathologic complete response (Version Date 11/20/23)

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## **IX Continuing Review**

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

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## **X Continuing Review**

**NRG-BR009**, A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score  $\leq 25$  (OFSET) (Version Date 07/27/23)

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## **XI 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 07/28/23)

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## **XII 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 10/17/23)

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## **XIII 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)

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## **XIV 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 02/10/23)

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