

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

**October 20, 2022**

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**I New Study - Initial Review**

**A012103**, OptimICE-PCR: De-Escalation of Therapy in Early-Stage TNBC Patients who Achieve pCR after Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy (Version Date 08/31/22)

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**II New Study - Initial Review**

**NRG-GY028**, A Phase IB and Randomized Phase II Trial of Megestrol Acetate with or without Ipatasertib in Recurrent or Metastatic Endometrioid Endometrial Cancer (Version Date 08/18/22)

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**III New Study - Initial Review**

**S2114**, A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T-Cell Treatment for Relapsed/Refractory Large B-Cell Lymphoma or Grade IIIB Follicular Lymphoma (Version Date 08/17/22)

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**IV Amendment**

**NRG-GY022**, Assessment of Carboplatin Clearance Predictors: A PK Study on NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Version Date 09/21/22)

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**V Continuing Review**

**EA8185**, Phase II Study of Bladder-Sparing Chemoradiation with Durvalumab in Clinical Stage III, Node Positive bladder Cancer (INSPIRE) (Version Date 07/11/22)

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## **VI Continuing Review**

**A031704**, PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE] (Version Date 08/16/22)

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## **VII Continuing Review**

**EA5182**, Randomized Phase III Study of Combination Osimertinib (AZD9291) and Bevacizumab versus Osimertinib (AZD9291) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC) (Version Date 04/14/21)

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## **VIII Continuing Review**

**A032001**, MAIN-CAV: Phase III Randomized Trial of Maintenance Cabozantinib and Avelumab vs Maintenance Avelumab After First-Line Platinum-Based Chemotherapy in Patients with Metastatic Urothelial Cancer (Version Date 06/28/22)

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## **IX Continuing Review**

**NRG-BN011**, A Phase III Trial of Lomustine-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients with Methylated MGMT Promoter Glioblastoma (Version Date 11/04/21)

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## **X Continuing Review**

**EA5163**, INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis (Version Date 10/25/21)

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## **XI Continuing Review**

**NRG-GI005**, Phase II/III Study of Circulating tumOr DNA as a Predictive BiomaRker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA) (Version Date 04/07/21)

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## **XII Continuing Review**

**A041501**, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (A Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL (Version Date 04/26/22)

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