

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

**March 16, 2023**

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**I New Study - Initial Review**

**EA8211**, Phase III Randomized Trial of Stereotactic Ablative Radiotherapy (SAbR) for Oligometastatic Advanced Renal Carcinoma (SOAR) (Version Date 01/26/23)

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**II Continuing Review**

**A021602**, Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo in Patients with Advanced Neuroendocrine Tumors After Progression on Prior Therapy (CABINET) (Version Date 02/03/23)

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**III Continuing Review**

**A021804**, A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma (Version Date 06/15/22)

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**IV Continuing Review**

**EAA173**, Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) (Version Date 07/29/21)

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**V Continuing Review**

**NRG-GU002**, Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation following Radical Prostatectomy with or without Adjuvant Docetaxel (Version Date 08/26/19)

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## **VI Continuing Review**

**NRG-GY021**, A Phase II Randomized Trial of Olaparib Versus Olaparib Plus Tremelimumab In Platinum-Sensitive Recurrent Ovarian Cancer (Version Date 08/27/21)

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## **VII Continuing Review**

**10272**, A Phase II Multi-Institutional Trial to Evaluate Prostate Specific Membrane Antigen (PSMA)-Based PET Imaging of High Risk Prostate Cancer (Version Date 04/18/22)

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## **VIII Continuing Review**

**A051301**, A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype (Version Date 03/22/22)

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## **IX Continuing Review**

**S1500**, A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET) (Version Date 09/06/22)

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## **X Continuing Review**

**S1609**, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Version Date 01/20/23)

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## **XI Continuing Review**

**S2005**, A Phase II Randomized Study of Ibrutinib and Rituximab with or without Venetoclax in Previously Untreated Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL) (Version Date 02/23/22)

## **XII Continuing Review**

**EA2174**, A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma (Version Date 01/05/23)

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## **XIII Continuing Review**

**N0577**, N0577 (CODEL): Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma (Version Date 03/10/22)

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## **XIV Continuing Review**

**S2107**, Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab (NSC #748726) for Patients with Previously Treated, Microsatellite Stable, BRAFV600E Metastatic and/or Unresectable Colorectal Cancer (Version Date 08/29/22)

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## **XV Continuing Review**

**A051701**, Randomized Phase II/III Study of Venetoclax (ABT 199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double-Expressing Lymphomas (Version Date 08/03/20)

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## **XVI Continuing Review**

**NRG-GY004**, A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Version Date 08/30/21)

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## **XVII Continuing Review**

**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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## **XVIII Continuing Review**

**NRG-GU012**, Randomized Phase II Stereotactic Ablative Radiation Therapy (SABR) for Metastatic Unresected Renal Cell Carcinoma (RCC) Receiving Immunotherapy (SAMURAI) (Version Date 02/20/23)

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## **XIX Continuing Review**

**NRG-BN007**, A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab versus Temozolomide in Patients with Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma (Version Date 01/17/23)

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