

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

**April 21, 2022**

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### **I Continuing Review**

**10272**, A Phase II Multi-Institutional Trial to Evaluate Prostate Specific Membrane Antigen (PSMA)-Based PET Imaging of High Risk Prostate Cancer (Protocol Version Date 10/08/21)

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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) (Protocol Version Date 07/24/20)

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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 (Protocol Version Date 09/15/21)

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### **IV 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 (Protocol Version Date 01/04/22)

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### **V Continuing Review**

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

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### **VI Continuing Review**

**EA2174**, A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma (Protocol Version Date 01/20/21)

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## **VII Continuing Review**

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

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## **VIII 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 (Protocol Version Date 03/10/22)

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## **IX 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 (Protocol Version Date 04/08/22)

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## **X Continuing Review**

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

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## **XI Continuing Review**

**NRG-GU005**, Phase III IGRT and SBRT vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer (Protocol Version Date 02/23/22)

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## **XII Continuing Review**

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

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## **XIII Continuing Review**

**NRG-GY022**, Assessment of Carboplatin Clearance Predictors: A PK Study on NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Protocol Version Date 08/11/21)

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**XIV Continuing Review**

**NRG-HN004**, Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Locoregionally Advanced Head and Neck Cancer with a Contraindication to Cisplatin (Protocol Version Date 03/09/22)

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**XV Continuing Review**

**NRG-HN007**, An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma (Protocol Version Date 02/16/21)

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**XVI 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) (Protocol Version Date 09/15/20)

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**XVII Continuing Review**

**S1609**, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Protocol Version Date 03/10/22)

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**XVIII Continuing Review**

**S1827**, MRI Brain Surveillance Alone versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK) (Protocol Version Date 05/04/21)

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**XIX 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) (Protocol Version Date 02/23/22)

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**XX New Study - Initial Review**

**S1900F**, A Randomized Phase II Study of Carboplatin and Pemetrexed with or Without Selpercatinib (LY3527723) in Participants with Non-Squamous RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer and Progression of Disease on Prior RET Directed Therapy (Lung-MAP Non-Match Sub-Study) (Protocol Version Date 03/03/22)

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**XXI Memos**

**LUNGMAP**, A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study) (Protocol Version Date 01/11/22)

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