

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

**October 21, 2021**

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### **I Continuing Review**

**A021703**, Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS) (Protocol Version Date 10/08/20)

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### **II Continuing Review**

**A031803**, Phase II Trial of Intravesical Gemcitabine and MK-3475 (pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (Protocol Version Date 02/26/21)

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### **III Continuing Review**

**E4402**, Randomized Phase III Trial Comparing Two Different Rituximab Dosing Regimens for Patients with Low Tumor Burden Indolent Non-Hodgkin's Lymphoma (Protocol Version Date 04/23/14)

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### **IV 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 (Protocol Version Date 03/01/21)

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### **V Continuing Review**

**EA1181**, (CompassHER2-pCR): Preoperative THP and postoperative HP in patients who achieve a pathologic complete response (Protocol Version Date 07/28/21)

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### **VI Continuing Review**

**EA2187**, A Phase 2 Study of Pevonedistat in Combination with Carboplatin and Paclitaxel in Advanced Intrahepatic Cholangiocarcinoma (Protocol Version Date 09/01/21)

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## **VII Continuing Review**

**NRG-BN003**, Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma (Protocol Version Date 12/17/19)

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## **VIII 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 (Protocol Version Date 06/07/21)

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## **IX New Study - Initial 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 (Protocol Version Date 09/08/21)

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## **X New Study - Initial Review**

**NRG-BN011**, A Phase III Trial of Lomustine-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients with Methylated MGMT Promoter Glioblastoma (Protocol Version Date 09/13/21)

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## **XI Amendment**

**NRG-GU008**, Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer after Radical Prostatectomy (INNOVATE) INTensifying treatment for NNode positive prostate cancer by VAring the hormonal ThERapy (Protocol Version Date 09/15/21)

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## **XII Amendment**

**NRG-GU009**, Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (PREDICT-RT) (Protocol Version Date 09/24/21)

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