

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

**March 18, 2021**

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**I Continuing Review**

**A031701**, A Phase II Study of Gemcitabine Plus Cisplatin Chemotherapy in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations (Protocol Version Date 01/13/21)

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**II Continuing Review**

**A151216**, Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) (Protocol Version Date 09/08/20)

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**III Continuing Review**

**ABTC-1802**, A Phase II Study of Binimetinib in Combination with Encorafenib in Adults with Recurrent BRAF V600-Mutated High-Grade Astrocytoma or other Primary Brain Tumor (Protocol Version Date 11/30/20)

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**IV Continuing Review**

**EA5191**, A Randomized Phase II Trial of Cabozantinib and Cabozantinib Plus Nivolumab Versus Standard Chemotherapy in Patients with Previously Treated Non-Squamous NSCLC (Protocol Version Date 04/07/20)

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**V Continuing Review**

**NRG-GU007**, Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with Initial Phase I) (Protocol Version Date 11/09/20)

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## **VI Continuing Review**

**NRG-GY005**, A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS) (Protocol Version Date 09/06/19)

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## **VII Continuing Review**

**S1706**, A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer (Protocol Version Date 05/15/20)

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## **VIII Continuing Review**

**S1826**, A Phase III, Randomized Study of Nivolumab (Opdivo) plus AVD or Brentuximab Vedotin (Adcetris) plus AVD in Patients (Age  $\geq$  12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma (Protocol Version Date 01/28/21)

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## **IX Amendment**

**A021502**, Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair (ATOMIC: Adjuvant Trial of Deficient Mismatch Repair in Colon Cancer) (Protocol Version Date 02/19/21)

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## **X Amendment**

**CCTG MA.39**, Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node T3N0 Positive Breast Cancer (Protocol Version Date 02/11/21)

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## **XI Amendment**

**S1007**, A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical



FOR THE NATIONAL CANCER INSTITUTE

Trial RX for Positive Node, Endocrine Responsive Breast Cancer (Protocol Version  
Date 12/23/20)

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## **XII Memos**

**9149**, Molecular Profiling-based Assignment of Cancer Therapy for Patients With Advanced  
Solid Tumors (Protocol Version Date 01/07/20)

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## **XIII Memos**

**A151216**, Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial  
(ALCHEMIST) (Protocol Version Date 09/08/20)

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