

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

**May 6, 2021**

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**I Continuing Review**

**EA2165**, A Randomized Phase III Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer (Protocol Version Date 02/10/21)

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**II Continuing Review**

**EA5161**, Randomized Phase II Clinical Trial of Cisplatin/Carboplatin and Etoposide (CE) Alone or in Combination with Nivolumab as Frontline Therapy for Extensive Stage Small Cell Lung Cancer (ED-SCLC) (Protocol Version Date 02/17/21)

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**III Continuing Review**

**EA6134**, DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) A Phase III Trial (Protocol Version Date 02/11/21)

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**IV Continuing Review**

**EA6192**, A Phase II Study of Biomarker Driven Early Discontinuation of Anti-PD-1 Therapy in Patients with Advanced Melanoma (PET-Stop) (Protocol Version Date 02/18/21)

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**V Continuing Review**

**EA8191**, Phase III Study of Local or Systemic Therapy INTensification DIrected by PET in Prostate CANcer Patients with Post-ProstaTEctomy Biochemical Recurrence (INDICATE) (Protocol Version Date 03/09/21)

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**VI Continuing Review**

**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 03/01/21)

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## **VII 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 (Protocol Version Date 08/15/19)

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## **VIII Continuing Review**

**NRG-GY006**, A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer (Protocol Version Date 02/17/21)

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## **IX Continuing Review**

**NRG-LU007**, RAnomized Phase II/III Trial Of Consolidation Radiation + Immunotherapy for ES-SCLC: RAPTOR trial (Protocol Version Date 03/30/21)

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## **X Continuing Review**

**S1619**, A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma (Protocol Version Date 03/20/19)

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## **XI Continuing Review**

**S1800A**, A Phase II Randomized Study of Ramucirumab plus Pembrolizumab (MK-3475) versus Standard of Care for Patients Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study) (Protocol Version Date 07/01/20)

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## **XII Continuing Review**

**S1802**, Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer (Protocol Version Date 01/06/21)

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### **XIII Continuing Review**

**S1900A**, A Phase II Study of Rucaparib in Patients with Genomic LOH High and/or Deleterious BRCA1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (LungMAP Sub-Study) (Protocol Version Date 12/14/20)

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### **XIV Continuing Review**

**S1900B**, A Phase II Study of Selpercatinib (LOXO-292) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (LungMAP Sub-Study) (Protocol Version Date 02/22/21)

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### **XV Continuing Review**

**S1900C**, A Phase II Study of Talazoparib plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations (LungMAP Sub-Study) (Protocol Version Date 12/04/20)

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### **XVI Continuing Review**

**S1900E**, A Phase II Study of Sotorasib (AMG 510) in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LungMAP Sub-Study) (Protocol Version Date 11/17/20)

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### **XVII Amendment**

**NRG-GY012**, A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer (Protocol Version Date 03/24/21)

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### **XVIII 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 03/01/21)

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