

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

**August 19, 2021**

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**I Continuing Review**

**A031801**, A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (RADICAL) (Protocol Version Date 10/30/20)

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**II Continuing Review**

**AMC-107**, A Phase 2 Trial of Ixazomib for Kaposi Sarcoma (Protocol Version Date 09/22/20)

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**III Continuing Review**

**EA1183**, FDG PET to Assess Therapeutic Response in Patients with Bone-dominant Metastatic Breast Cancer, FEATURE (Protocol Version Date 11/23/20)

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**IV Continuing Review**

**EA2183**, A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA) (Protocol Version Date 12/18/19)

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**V Continuing Review**

**EA3163**, Phase II randomized trial of neoadjuvant chemotherapy followed by surgery and post-operative radiation versus surgery and post-operative radiation for organ preservation of T3 and T4a (and selected T4b) nasal and paranasal sinus squamous cell carcinoma (NPNSCC) (Protocol Version Date 01/21/21)

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**VI Continuing Review**

**EA9152**, A Phase Ib/II Study of Venetoclax (ABT-199) in Combination with Liposomal Vincristine in Patients with Relapsed or Refractory T-cell or B-cell Acute Lymphoblastic Leukemia (Protocol Version Date 05/28/21)

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## **VII Continuing Review**

**EA9181**, A Phase III Randomized Trial of Steroids +Tyrosine Kinase Inhibitor Induction with Chemotherapy or Blinatumomab for Newly Diagnosed BCR-ABL-positive Acute Lymphoblastic Leukemia in Adults (Protocol Version Date 09/14/20)

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## **VIII Continuing Review**

**GOG-0262**, A Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel In Combination With Carboplatin With Or Without Concurrent and Consolidation Bevacizumab (NSC #704865, IND #113912) in the Treatment of Primary Stage II, III OR IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer and ACRIN 6695: Perfusion CT Imaging To Evaluate Treatment Response in Patients Participating in GOG-0262 (Protocol Version Date 11/07/18)

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## **IX Continuing Review**

**NRG-GI003**, A Phase III Randomized Trial of Protons versus Photons for Hepatocellular Carcinoma (Protocol Version Date 10/18/19)

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## **X Continuing Review**

**NRG-LU002**, Maintenance Systemic Therapy versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial (Protocol Version Date 07/19/21)

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## **XI Continuing Review**

**S1702**, A Phase II Study of Isatuximab (SAR650984) (NSC-795145) for Patients with Previously Treated AL Amyloidosis (Protocol Version Date 07/10/19)

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## **XII New Study - Initial Review**

**A092001**, Phase 2 Randomized Trial of Neoadjuvant or Palliative Chemotherapy with or Without Immunotherapy for Peritoneal Mesothelioma (Protocol Version Date 07/14/21)

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### **XIII New Study - Initial Review**

**NRG-GI008**, Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (CIRCULATE-US) (Protocol Version Date 07/13/21)

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### **XIV Amendment**

**NRG-HN001**, Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA) (Protocol Version Date 06/28/21)

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