

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

**July 7, 2022**

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### **I Continuing Review**

**A041702**, A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib plus Venetoclax and Obinutuzumab in Untreated Older Patients ( $\geq$  65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 04/18/22)

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### **II Continuing Review**

**EA9161**, A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 02/22/22)

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### **III 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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### **IV Continuing Review**

**NRG-BR004**, A Randomized, Double-Blind, Phase III Trial of Taxane/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer (Protocol Version Date 01/14/22)

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### **V Continuing Review**

**RTOG-0924**, Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial (Protocol Version Date 12/13/18)

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**VI Continuing Review**

**S1801**, A Phase II Randomized Study of Adjuvant versus Neoadjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High Risk Melanoma (Protocol Version Date 02/11/22)

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**VII New Study - Initial Review**

**A092104**, A Randomized Phase 2/3 Study of Olaparib plus Temozolomide versus Investigator's Choice for the Treatment of Patients with Advanced Uterine Leiomyosarcoma after Progression on Prior Chemotherapy (Protocol Version Date 05/10/22)

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**VIII New Study - Initial Review**

**EA9211**, A Phase II Study of Oral Arsenic Trioxide and All-Trans Retinoic Acid Consolidation Treatment for High Risk Acute Promyelocytic Leukemia (APL) (Protocol Version Date 05/25/22)

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**IX New Study - Initial Review**

**NRG-BN012**, A Randomized Phase III Trial of Pre-Operative Compared to Post-Operative Stereotactic Radiosurgery in Patients with Resectable Brain Metastases (Protocol Version Date 05/17/22)

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