

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

**December 1, 2022**

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**I New Study - Initial Review**

**A022101**, A Pragmatic Randomized Phase III Trial Evaluating Total Ablative Therapy for Patients with Limited Metastatic Colorectal Cancer: Evaluating Radiation, Ablation, and Surgery (ERASur) (Version Date 10/17/22)

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**II New Study - Initial Review**

**NRG-BR008**, Phase III Randomized Trial of Radiotherapy Optimization for Low-Risk HER2-Positive Breast Cancer (HERO) (Version Date 09/30/22)

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**III New Study - Initial Review**

**S1900G**, A Randomized Phase II Study of INC280 (capmatinib) plus Osimertinib with or without Ramucirumab in Participants with EGFR-Mutant, MET-Amplified Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study) (Version Date 10/11/22)

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**IV 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) (Version Date 11/03/22)

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**V Continuing Review**

**A011202**, A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy (Version Date 06/07/22)

## **V Continuing Review**

**A031102**, A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors (Version Date 07/23/21)

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## **VI Continuing Review**

**A041202**, A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients ( $\geq 65$  Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Version Date 12/21/21)

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## **VII Continuing Review**

**A081801**, Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO) (Version Date 08/15/22)

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## **VIII Continuing Review**

**EAA171**, Optimizing Prolonged Treatment In Myeloma Using MRD Assessment (OPTIMUM) (Version Date 05/27/22)

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## **IX Continuing Review**

**GOG-0213**, A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel (Or Gemcitabine) Alone or in Combination with Bevacizumab (NSC #704865, IND #113912) followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer. NCI-Supplied Agents: Bevacizumab (NSC #704865, IND #113912) NCT# 00565851 (Version Date 11/16/18)

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## **X Continuing Review**

**GOG-0263**, Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy (Version Date 03/14/22)

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## **XI Continuing Review**

**NRG-GY012**, A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combinations of Cediranib/Olaparib, Olaparib/Durvalumab (MEDI4736), Cediranib/Durvalumab (MEDI4736), Olaparib/AZD5363 (Capivasertib) in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. A Multi-Arm Trial for Women with Recurrent or Persistent Endometrial Cancer (Version Date 04/27/22)

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## **XII Continuing Review**

**NRG-GY019**, A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum (Version Date 11/14/22)

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## **XIII Continuing Review**

**NRG-LU005**, Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab (Version Date 11/03/22)

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## **XIV Continuing Review**

**S1403**, A Randomized Phase II Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC) (BI 1200.124) (Version Date 09/26/22)

## **XV Continuing Review**

**S1929**, Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC) (Version Date 01/13/22)

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## **XVI Continuing Review**

**S1905**, A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL) (Version Date 01/05/22)

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## **XVII Continuing Review**

**E1912**, A Randomized Phase III Study of Ibrutinib (PCI- 32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Version Date 12/29/21)

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