

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

**December 4, 2025**

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### **I New Study - Initial Review**

**A042302**, Phase III Evaluation of Fixed Duration Zanubrutinib plus Sonrotoclax-Based Therapy Compared to Continuous Zanubrutinib in Previously Untreated Older Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) (Version Date 09/11/25)

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### **II Continuing Review**

**10272**, A Phase II Multi-Institutional Trial to Evaluate Prostate Specific Membrane Antigen (PSMA)-Based PET Imaging of High Risk Prostate Cancer (Version Date 08/21/25)

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### **III Continuing Review**

**A021602**, Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo in Patients with Advanced Neuroendocrine Tumors After Progression on Prior Therapy (CABINET) (Version Date 07/16/25)

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### **IV Continuing Review**

**A021804**, A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma (Version Date 10/22/25)

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### **V Continuing Review**

**EA2174**, A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma (Version Date 08/06/25)

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## **VI Continuing Review**

**EA6134**, DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) A Phase III Trial (Version Date 07/30/25)

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## **VII Continuing Review**

**EA6192**, A Phase II Study of Biomarker Driven Early Discontinuation of Anti-PD-1 Therapy in Patients with Advanced Melanoma (PET-Stop) (Version Date 07/30/25)

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## **VIII Continuing Review**

**EA7211**, A Randomized Phase III Study of Neoadjuvant Chemotherapy followed by Surgery versus Surgery Alone for Patients with High Risk RetroPeritoneal Sarcoma (STRASS 2) (Version Date 04/02/25)

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## **IX Continuing Review**

**NRG-GU002**, Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation following Radical Prostatectomy with or without Adjuvant Docetaxel (Version Date 12/20/24)

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## **X Continuing Review**

**NRG-GU012**, Randomized Phase II Stereotactic Ablative Radiation Therapy (SABR) for Metastatic Unresected Renal Cell Carcinoma (RCC) Receiving Immunotherapy (SAMURAI) (Version Date 07/28/25)

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## **XI Continuing Review**

**NRG-LU007**, RANdomized Phase II/III Trial Of Consolidation Radiation + Immunotherapy for ES-SCLC: RAPTOR trial (Version Date 03/13/25)

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## **XII 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) (Version Date 12/16/24)

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## **XIII Continuing Review**

**S1800D**, A Phase II/III Study of N-803 (ALT-803) Plus Pembrolizumab Versus Standard of Care in Participants with Stage IV or Recurrent Non-Small Cell Lung Cancer Previously Treated with Anti-PD-1 or Anti-PD-L1 Therapy (Lung-MAP Non-Match Sub-Study) (Version Date 04/17/25)

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## **XIV Continuing Review**

**S1609**, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Version Date 07/28/25)

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## **XV Continuing Review**

**S1827**, MRI Brain Surveillance Alone versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK) (Version Date 08/01/25)

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## **XVI Continuing Review**

**S2005**, A Phase II Randomized Study Comparing Ibrutinib and Rituximab vs. Venetoclax and Rituximab in Previously Untreated Waldenström's Macroglobulinemia (WM) /Lymphoplasmacytic Lymphoma (LPL) (Version Date 05/28/25)

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## **XVII Continuing Review**

**S1800E**, A Randomized Phase II/III Study of Docetaxel and Ramucirumab with or without Cemiplimab (REGN2810) for Participants Previously Treated with Platinum-Based Chemotherapy and Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study) (Version Date 10/02/25)

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## **XVIII Continuing Review**

**S1900B**, A Phase II Study of Selpercatinib (LY3527723) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (LungMAP Sub-Study) (Version Date 09/24/24)

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## **XIX Continuing Review**

**S2107**, Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab (NSC #748726) for Patients with Previously Treated, Microsatellite Stable, BRAFV600E Metastatic and/or Unresectable Colorectal Cancer (Version Date 07/18/25)

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## **XX Continuing Review**

**S2303**, Randomized Phase II/III Trial of 2nd Line Nivolumab + Paclitaxel + Ramucirumab versus Paclitaxel + Ramucirumab in Patients with PD-L1 CPS  $\geq 1$  Advanced Gastric and Esophageal Adenocarcinoma (PARAMUNE) (Version Date 07/18/25)

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## **XXI 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) (Version Date 11/20/24)

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## **XXII Continuing Review**

**S1900G**, A Randomized Phase II Study of 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 07/10/25)

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## **XXIII Continuing Review**

**S2414**, Randomized Phase III Trial INcorporating Pathologic Complete ReSponse in Participants with Early StaGe Non-Small Cell Lung Cancer to Optimize ImmunotHerapy in the AdjuvanT Setting (INSIGHT) (Version Date 03/11/25)

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## **XXIV Continuing Review**

**S1900J**, A Phase II Study of Amivantamab Hyaluronidase in Participants with MET Amplification-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study) (Version Date 06/25/25)

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## **XXV Continuing Review**

**S1900K**, A Randomized Phase II Study of Tepotinib with or without Ramucirumab in Participants with MET Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study) (Version Date 12/16/24)

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