

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

**September 19, 2024**

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**I New Study - Initial Review**

**CCTG-PR26**, A Randomized Phase III Clinical Trial for the Addition of Docetaxel to Androgen Receptor Pathway Inhibitors in Patients with Metastatic Castration Sensitive Prostate Cancer and Suboptimal PSA Response (TRIPLE-SWITCH) (Version Date 08/22/24)

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**II New Study - Initial Review**

**A092205**, Randomized Phase III Trial of Pembrolizumab vs. Pembrolizumab/Cetuximab in Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma with Platinum Refractory Disease (Version Date 08/19/24)

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**III Amendment**

**NRG-HN010**, A Phase II Trial of HER2-Targeted Therapies for Recurrent, Metastatic, or Unresectable HER2-Expressing Salivary Gland Cancers (Version Date 08/09/24)

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**IV Amendment**

**S2015**, Melanoma Margins Trial (MelMarT-II): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma (Version Date 08/15/24)

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**V Continuing Review**

**A022106**, Phase II/III Second-Line NABPLAGEM vs. Nab-Paclitaxel/Gemcitabine in BRCA1/2 or PALB2 Mutant Metastatic Pancreatic Ductal Adenocarcinoma (PLATINUM) (Version Date 09/28/23)

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## **VI Continuing Review**

**A022104**, The Janus Rectal Cancer Trial: A Randomized Phase II/III Trial Testing the Efficacy of Triplet Versus Doublet Chemotherapy Regarding Clinical Complete Response and Disease-Free Survival in Patients with Locally Advanced Rectal Cancer (Version Date 05/21/24)

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## **VII Continuing Review**

**A032001**, MAIN-CAV: Phase III Randomized Trial of Maintenance Cabozantinib and Avelumab vs Maintenance Avelumab After First-Line Platinum-Based Chemotherapy in Patients with Metastatic Urothelial Cancer (Version Date 10/04/23)

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## **VIII Continuing Review**

**A041501**, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (A Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL (Version Date 02/07/24)

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## **IX 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 01/20/23)

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## **X Continuing Review**

**EA5163**, INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis (Version Date 07/14/23)

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## **XI Continuing Review**

**EA5182**, Randomized Phase III Study of Combination Osimertinib (AZD9291) and Bevacizumab versus Osimertinib (AZD9291) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC) (Version Date 09/05/24)

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## **XII Continuing Review**

**NRG-BN011**, A Phase III Trial of Lomustine-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients with Methylated MGMT Promoter Glioblastoma (Version Date 05/09/23)

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## **XIII Continuing Review**

**NRG-HN011**, A Randomized Phase II Study of Nivolumab Versus Nivolumab and BMS-986016 (Relatlimab) as Maintenance Treatment After First-Line Treatment with Platinum-Gemcitabine-Nivolumab for Patients with Epstein-Barr Virus-Associated Recurrent/Metastatic Nasopharyngeal Carcinoma (REMAIN) (Version Date 07/16/24)

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## **XIV Continuing Review**

**S1608**, Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma (Version Date 10/06/22)

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## **XV 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)

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**XVI Continuing Review**

**S1933**, A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status (Version Date 10/11/23)

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**XVII Continuing Review**

**S1925**, Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study (Version Date 04/10/24)

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