

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

**October 17, 2024**

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**I New Study - Initial Review**

**A032201**, Short TeRm Intensified Pembrolizumab (KEytruda) and Tivozanib for High-Risk Renal Cell Carcinoma - STRIKE (Version Date 09/17/24)

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**II Amendment**

**A021804**, A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma (Version Date 08/23/24)

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**III Amendment ReReview**

**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 10/01/24)

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**IV 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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**V Continuing Review**

**EA8134**, InPACT- International Penile Advanced Cancer Trial (International Rare Cancers Initiative Study) (Version Date 03/22/24)

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## **VI Continuing Review**

**A081801**, Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO) (Version Date 09/01/23)

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## **VII Continuing Review**

**A091903**, A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma (Version Date 01/26/24)

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## **VIII Continuing Review**

**A092107**, A Randomized Phase 2 Trial with a Safety Lead-In to Evaluate Palbociclib versus Palbociclib and Cemiplimab for the Treatment of Advanced Dedifferentiated Liposarcoma (Version Date 09/04/24)

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## **IX 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 05/23/24)

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## **X 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 06/06/24)

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## **XI Continuing Review**

**NRG-GY025**, A Randomized Phase II Trial of Nivolumab and Ipilimumab Compared to Nivolumab Monotherapy in Patients with Deficient Mismatch Repair System Recurrent Endometrial Carcinoma (Version Date 09/24/24)

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## **XII Continuing Review**

**A022004**, Randomized Trial of Consolidation Targeted Adjuvant Therapy with Encorafenib and Cetuximab versus Usual Care for Patients with Stage II/III BRAF V600E Colon Cancer (Version Date 08/14/24)

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## **XIII Continuing Review**

**MM1YA-CTG01**, A Measurable Residual Disease (MRD) Focused, Phase II Study of Venetoclax plus Chemotherapy for Newly Diagnosed Younger Patients with Intermediate Risk Acute Myeloid Leukemia: A Tier 1 MyeloMATCH Clinical Trial (Version Date 06/12/24)

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## **XIV Continuing Review**

**EA9213**, A Phase II Study of Daratumumab-Hyaluronidase for Chemotherapy-Relapsed/Refractory Minimal Residual Disease (MRD) in T Cell Acute Lymphoblastic Leukemia (T-ALL) (Version Date 03/11/22)

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