

Adult CIRB - Late Phase Emphasis Meeting Agenda

October 2, 2025

I New Study - Initial Review

A082402, Involved-Station, Intensity-Modulated Post-Operative Radiation Therapy (I²-PORT) for Resected Non-Small Cell Lung Cancer with Residual Mediastinal Adenopathy After Neoadjuvant Therapy (ypN2) (Version Date 08/29/25)

II New Study - Initial Review

NRG-HN015, A Phase II Randomized Trial of NEOadjuvant Chemotherapy or ChemO-Immunotherapy in Patients with Recurrent/Persistent PD-L1 Enriched Squamous Cell Carcinoma of the Head and Neck Undergoing Salvage Surgery (NEOPOLIS) (Version Date 09/05/25)

III New Study - Initial Review

NRG-GY035, A Randomized Phase III Trial of Carboplatin, Paclitaxel, Pembrolizumab versus Carboplatin, Paclitaxel, Bevacizumab versus Carboplatin, Paclitaxel, Pembrolizumab, Bevacizumab in the Treatment of pMMR, TP53 Mutated Advanced or Recurrent Endometrial Cancer (Version Date 09/03/25)

IV Amendment

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 08/21/25)

V Continuing Review

A012301, LoTam: A Randomized, Phase III Clinical Trial of Low-Dose Tamoxifen for Selected Patients with Molecular Low-Risk Early-Stage Breast Cancer (Version Date 07/15/25)

VI Continuing Review

A022102, Randomized Phase III trial of mFOLFIRINOX +/- Nivolumab vs. FOLFOX +/- Nivolumab for First-Line Treatment of Metastatic HER2-Negative Gastroesophageal Adenocarcinoma (Version Date 07/16/25)

VII Continuing Review

A031704, PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE] (Version Date 08/01/25)

VIII Continuing Review

A032101, A Phase 2 Trial of ADT Interruption in Patients Responding Exceptionally to AR-Pathway Inhibitor in Metastatic Hormone-Sensitive Prostate Cancer (MHSPC): A-DREAM (Version Date 08/19/25)

IX Continuing Review

A032201, Short TeRm Intensified Pembrolizumab (KEytruda) and Tivozanib for High-Risk Renal Cell Carcinoma - STRIKE (Version Date 04/22/25)

X Continuing Review

EA5221, A Randomized Phase III Trial of Chemo Immunotherapy vs Immunotherapy Alone for the Vulnerable Older Adult with Advanced Non-Small Cell Lung Cancer: The ACHIEVE Study (Version Date 06/06/25)

XI Continuing Review

NRG-GY005, A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS) (Version Date 07/27/23)

XII Continuing Review

NRG-GY023, A Randomized Phase II Trial of Triplet Therapy (A PD-L1 Inhibitor Durvalumab (MEDI4736) in Combination with Olaparib and Cediranib) Compared to Olaparib and Cediranib or Durvalumab (MEDI4736) and Cediranib or Standard of Care Chemotherapy in Women with Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer who have Received Prior Bevacizumab (Version Date 05/23/24)

XIII Continuing Review

NRG-GY032, A Phase II Study of Tailored Adjuvant Therapy in Pole-Mutated and p53-Wildtype/NSMP Early-Stage Endometrial Cancer (RAINBO BLUE & TAPER) (Version Date 07/31/25)

XIV Continuing 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 04/22/25)

XV Continuing Review

NRG-BN010, A Safety Run-In and Phase II Study Evaluating the Efficacy, Safety, and Impact on the Tumor Microenvironment of the Combination of Tocilizumab, Atezolizumab, and Fractionated Stereotactic Radiotherapy in Recurrent Glioblastoma (Version Date 08/04/25)

XVI Continuing Review

S0777, A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant (Version Date 08/12/24)

XVII Continuing Review

S1400, A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-Map) (Version Date 12/18/20)
