



Adult CIRB - Late Phase Emphasis Meeting Agenda

September 4, 2025

I New Study - Initial Review

A032304, Radioligand Efficacy Comparison by Initial PSA-Response Outcome in Metastatic CRPC with Lutetium 177LU PSMA RLT (RECIPROCAL) (Version Date 07/15/25)

II New Study - Initial Review

MM10A-MDS-A05, A Randomized Phase II Trial of Olutasidenib-Based Therapies in Patients with Newly Diagnosed IDH1-Mutant Myeloid Malignancies: A MyeloMATCH Substudy (Version Date 07/22/25)

III New Study ReReview

A072301, Phase III Trial of Radiotherapy Followed by Adjuvant Temozolomide in Combination with the IDH Inhibitor Vorasidenib vs Placebo in IDH-Mutated Newly-Diagnosed Grade 3 Astrocytomas (Version Date 08/12/25)

IV Amendment

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)

V Continuing Review

A012103, OptimICE-PCR: De-Escalation of Therapy in Early-Stage TNBC Patients who Achieve pCR after Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy (Version Date 04/22/25)

VI Continuing Review

A071701, Genomically-Guided Treatment Trial in Brain Metastases (Version Date 12/20/24)

VII Continuing Review

CCTG CE.7, A Phase III Trial of Stereotactic Radiosurgery Compared with Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) Plus Memantine for 5 or More Brain Metastases (Version Date 04/01/22)

VIII 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)

IX Continuing Review

GOG-0281, A Randomized Phase II/III Study To Assess The Efficacy of Trametinib (GSK 1120212) In Patients With Recurrent Or Progressive Low-Grade Serous Ovarian Cancer Or Peritoneal Cancer. NCT # NCT02101788 (Version Date 09/19/22)

X Continuing Review

S2302, Pragmatica - Lung: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) plus Pembrolizumab (MK-3475; NSC 776864) versus Standard of Care for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Version Date 04/11/25)

XI Continuing Review

MM1MDS-A01, A Randomized Phase II Trial of Enasidenib-Based Therapies Versus Cedazuridine-Decitabine in Higher-Risk IDH2-Mutated Myelodysplastic Syndrome: A MyeloMATCH Sub-Study (Version Date 03/03/25)

XII 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)

XIII 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)

XIV Continuing Review

NRG-GY033, A Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Combination with Leuprolide Acetate and Exemestane in Recurrent Adult-Type Ovarian Granulosa Cell Tumor (Version Date 05/01/24)

XV 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 06/02/25)

XVI 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 Substudy (Version Date 03/17/25)
