

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 6, 2026

I New Study - Initial Review

A062501, Bispecific Antibody Therapy vs Autologous Stem Cell Transplantation as Consolidation for Newly Diagnosed, Standard Risk Multiple Myeloma (Version Date 06/12/26)

II 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 11/19/25)

III Continuing Review

A032304, Radioligand Efficacy Comparison by Initial PSA-Response Outcome in Metastatic CRPC with Lutetium 177LU PSMA RLT (RECIPROCAL) (Version Date 09/26/25)

IV 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)

V Continuing Review

NRG-GI012, Phase III Randomized Trial of IO-Based Systemic Treatment +/- Liver SBRT in Hepatocellular Cancer with Macrovascular Invasion (HELIO-RT) (Version Date 09/10/25)

VI 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 06/02/26)

VII 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)

VIII 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 07/24/25)

IX 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)

X 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 03/30/26)

XI 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 02/09/26)
