

Adult CIRB - Late Phase Emphasis Meeting Agenda

May 1, 2025

I New Study - Initial Review

A032303, GAIN-BCG: Gemcitabine Alternating with INtravesical BCG Randomized Against BCG Alone for Patients with Recurrent High Grade Non-Muscle Invasive Bladder Cancer (Version Date 03/25/25)

II Continuing Review

A071702, A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermutated Recurrent WHO Grade 4 Glioma (Version Date 09/06/23)

III Continuing Review

A151804, Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events (Version Date 06/03/24)

IV Continuing Review

CCTG-HN11, SPECT-CT Guided Elective Contralateral Neck Treatment (Select) for Patients with Lateralized Oropharyngeal Cancer: A Phase III Randomized Controlled Trial (Version Date 08/22/22)

V Continuing Review

NRG-GI003, A Phase III Randomized Trial of Protons versus Photons for Hepatocellular Carcinoma (Version Date 08/10/22)

VI Continuing Review

NRG-GU008, Randomized Phase III Trial Incorporating Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer after Radical Prostatectomy (INNOVATE*) (Version Date 08/13/24)

VII Continuing Review

E4512, A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein (Version Date 02/13/24)

VIII Continuing Review

NRG-GU010, Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE) (Version Date 05/06/24)

IX Continuing Review

A091802, Phase II Randomized Trial of Avelumab Plus Cetuximab versus Avelumab Alone in Advanced Cutaneous Squamous Cell Carcinoma of the Skin (cSCC) (Version Date 10/03/23)

X Continuing Review

NRG-LU003, A Biomarker-Driven Protocol for Previously Treated ALK-Positive Non-Squamous NSCLC Patients: The NCI-NRG ALK Protocol (Version Date 11/14/24)

XI Continuing Review

EA3202, A Phase II/III Trial of Chemotherapy + Cetuximab vs Chemotherapy + Bevacizumab vs Atezolizumab + Bevacizumab Following Progression on Immune Checkpoint Inhibition in Recurrent/Metastatic Head and Neck Cancers (Version Date 03/13/25)

XII Continuing Review

NRG-HN009, Protocol NRG-HN009, Randomized Phase II/III Trial of Radiation with Cisplatin at 100 mg/m² Every Three Weeks versus Radiation with Weekly Cisplatin at 40 mg/m² for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN) (NCT05050162) (Version Date 10/25/22)

XIII Continuing Review

A041701, A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy (Version Date 08/12/24)

XIV Continuing Review

S1937, A Phase III Randomized Trial of Eribulin (NSC #707389) with Gemcitabine versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy (Version Date 12/13/24)

XV Continuing Review

S2213, A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis (Version Date 02/19/24)

XVI Continuing Review

S1613, A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (MCRC) with HER-2 Amplification (Version Date 10/01/24)

XVII Continuing Review

S1803, Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC STUDY) (Version Date 06/03/24)

XVIII Continuing Review

S2001, Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations (Version Date 10/24/24)

XIX Continuing Review

S2007, A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases (Version Date 01/06/25)

XX Continuing Review

S2101, Biomarker Stratified CaboZantinib (NSC#761968) and NivOlumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Participants with Advanced Solid Tumors (IO Refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers - an immunoMATCH Pilot Study (Version Date 03/28/25)
