

Adult CIRB - Late Phase Emphasis Meeting Agenda

June 6, 2024

I New Study - Initial Review

NRG-GY036, A Phase III Trial of One vs. Two Years of Maintenance Olaparib, with or without Bevacizumab, in Patients with BRCA1/2 Mutated or Homologous Recombination Deficient (HRD+) Ovarian Cancer Following Response to First Line Platinum-Based Chemotherapy (Version Date 04/25/24)

II New Study - Initial Review

S2312, A Phase III Study of Cabazitaxel with or without Carboplatin in Patients with Metastatic Castrate Resistant Prostate Cancer (MCRPC), Stratified by Aggressive Variant Signature (Version Date 04/24/24)

III 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 08/18/21)

IV 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)

V 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)

VI Continuing Review

A092104, A Randomized Phase 2/3 Study of Olaparib plus Temozolomide versus Investigator's Choice for the Treatment of Patients with Advanced Uterine Leiomyosarcoma after Progression on Prior Chemotherapy (Version Date 12/14/23)

VII Continuing Review

A151804, Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events (Version Date 08/02/23)

VIII 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)

IX 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)

X 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 10/19/23)

XI Continuing Review

EA8212, A Randomized Phase III Trial of Intravesical BCG versus Intravesical Docetaxel and Gemcitabine Treatment in BCG Naïve High Grade Non-Muscle Invasive Bladder Cancer (BRIDGE) (Version Date 04/01/24)

XII Continuing Review

NRG-BN009, Phase III Trial of Stereotactic Radiosurgery (SRS) or Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for Distant Brain Relapse With Brain Metastasis Velocity ≥ 4 Brain Metastases/Year (Version Date 04/06/23)

XIII Continuing Review

NRG-BN012, A Randomized Phase III Trial of Pre-Operative Compared to Post-Operative Stereotactic Radiosurgery in Patients with Resectable Brain Metastases (Version Date 01/20/23)

XIV Continuing Review

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

XV 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 05/30/23)

XVI 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)

XVII 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)

XVIII Continuing Review

NRG-LU003, A Biomarker-Driven Protocol for Previously Treated ALK-Positive Non-Squamous NSCLC Patients: The NCI-NRG ALK Protocol (Version Date 01/20/22)

XIX 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 01/07/22)

XX 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 05/18/23)

XXI 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 09/29/23)

XXII 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 12/04/23)

XXIII 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 12/06/23)
