

Adult CIRB - Late Phase Emphasis Meeting Agenda

July 6, 2023

I New Study - Initial Review

NRG-BR009, A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score ≤ 25 (OFSET) (Version Date 06/01/23)

II New Study - Initial Review

S1900K, A Randomized Phase II Study of Tepotinib with or without Ramucirumab in Participants with MET Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study) (Version Date 05/26/23)

III New Study - Initial Review

S2206, Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive/Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer (Version Date 05/03/23)

IV Amendment

EA2205, A Randomized Phase II Trial Evaluating Chemotherapy vs Chemotherapy plus Bevacizumab and Atezolizumab in Advanced Combined Hepatocellular Carcinoma-Cholangiocarcinoma (Version Date 05/24/23)

V Continuing Review

A071702, A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermutated Recurrent WHO Grade 4 Glioma (Version Date 01/20/23)

VI 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 07/18/22)

VII 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 10/26/22)

VIII Continuing Review

A151804, Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events (Version Date 09/27/21)

IX 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)

X 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 02/10/23)

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 01/12/23)

XII Continuing Review

EAA181, Effective Quadruplet Utilization After Treatment Evaluation (EQUATE): A Randomized Phase 3 Trial for Newly Diagnosed Multiple Myeloma Not Intended for Early Autologous Transplantation (Version Date 09/16/21)

XIII 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)

XIV 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)

XV Continuing Review

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

XVI 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)

XVII 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 06/02/23)

XVIII 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)

XIX 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)

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 09/30/22)

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 02/15/23)

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 11/22/22)

XXIII 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)
