

Adult CIRB - Late Phase Emphasis Meeting Agenda

December 7, 2023

I New Study - Initial Review

A062101, Phase I/II Study of the Safety, Tolerability and Efficacy of Belantamab Mafodotin (GSK2857916) in Combination with Iberdomide (CC-220)/Dexamethasone versus Belantamab Mafodotin (GSK2857916)/Dexamethasone in Relapsed Refractory Multiple Myeloma (Version Date 11/01/23)

II New Study - Initial Review

S2306, A Randomized Phase 2 Trial to Evaluate the Efficacy of BCL-2 Inhibitor Therapy with Chemotherapy Compared to Chemotherapy Alone in Adult Patients with Newly Diagnosed T-Cell ALL and T-Cell Lymphoblastic Lymphoma (Version Date 10/09/23)

III Amendment

A031704, PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE] (Version Date 10/03/23)

IV Continuing Review

A021502, Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair (ATOMIC: Adjuvant Trial of Deficient Mismatch Repair in Colon Cancer) (Version Date 10/02/23)

V Continuing Review

A021806, A Phase III Trial of Perioperative versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer (Version Date 03/23/23)

V Continuing Review

A022101, A Pragmatic Randomized Phase III Trial Evaluating Total Ablative Therapy for Patients with Limited Metastatic Colorectal Cancer: Evaluating Radiation, Ablation, and Surgery (ERASur) (Version Date 09/07/23)

VI Continuing Review

A071601, Phase II Trial of BRAF/MEK Inhibitors in Papillary Craniopharyngiomas (Version Date 02/03/23)

VII Continuing Review

A151216, Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) (Version Date 09/01/23)

VIII Continuing Review

E4A03, A Randomized Phase III Study of CC-5013 Plus Dexamethasone Versus CC-5013 Plus Low Dose Dexamethasone in Multiple Myeloma with Thalidomide Plus Dexamethasone Salvage Therapy for Non-Responders (Version Date 09/27/19)

IX Continuing Review

EA2192, APOLLO: A Randomized Phase II Double-Blind Study of Olaparib versus Placebo Following Curative Intent Therapy in Patients with Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation (Version Date 10/02/23)

X Continuing Review

EA2205, A Randomized Phase II Trial Evaluating Chemotherapy plus Atezolizumab vs Chemotherapy plus Bevacizumab and Atezolizumab in Advanced Combined Hepatocellular Carcinoma-Cholangiocarcinoma (Version Date 10/18/23)

XI Continuing Review

EA5191, A Randomized Phase II Trial of Cabozantinib and Cabozantinib Plus Nivolumab Versus Standard Chemotherapy in Patients with Previously Treated Non-Squamous NSCLC (Version Date 08/22/23)

XII Continuing Review

EA6194, Phase II Randomized Study of Neoadjuvant Pembrolizumab Alone or in Combination with CMP-001 in Patients with Operable Melanoma: Efficacy and Biomarker Study (Version Date 05/31/23)

XIII Continuing Review

EA8153, Cabazitaxel with Abiraterone versus Abiraterone alone Randomized Trial for Extensive Disease following Docetaxel: the CHAARTED2 Trial (Version Date 09/17/21)

XIV Continuing Review

NRG-BR008, Phase III Randomized Trial of Radiotherapy Optimization for Low-Risk HER2-Positive Breast Cancer (HERO) (Version Date 02/23/23)

XV Continuing Review

NRG-GU007, Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with Initial Phase I) (Version Date 05/24/22)

XVI Continuing Review

NRG-GY005, A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS) (Version Date 07/27/23)

XVII Continuing Review

NRG-GY018, A Phase III Randomized, Placebo-Controlled Study of Pembrolizumab (MK-3475, NSC #776864) in Addition to Paclitaxel and Carboplatin for Measurable Stage III or IVA, Stage IVB or Recurrent Endometrial Cancer (Version Date 02/24/23)

XVIII Continuing Review

NRG-GY023, A Randomized Phase II Trial of Triplet Therapy (A PD-L1 Inhibitor Durvalumab (MEDI4736) in Combination with Olaparib and Cediranib) Compared to Olaparib and Cediranib or Durvalumab (MEDI4736) and Cediranib or Standard of Care Chemotherapy in Women with Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer who have Received Prior Bevacizumab (Version Date 07/25/23)

XIX Continuing Review

NRG-HN006, Randomized Phase II/III Trial of Sentinel Lymph Node Biopsy versus Elective Neck Dissection for Early-Stage Oral Cavity Cancer (Version Date 01/14/22)

XX Continuing Review

RTOG-1112, Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma (Version Date 09/23/22)

XXI Continuing Review

S0777, A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant (Version Date 09/03/19)

XXII Continuing Review

S1400, A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-Map) (Version Date 12/18/20)

XXIII Continuing Review

S1602, A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer (Version Date 07/22/19)

XXIV Continuing Review

S1706, A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer (Version Date 07/26/23)

XXV Continuing Review

S1918, A Phase II/III Randomized Study of R-miniCHOP with or without CC-486 (Oral Azacitidine) in Participants Age 75 Years or Older with Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIb Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-Cell Lymphomas with MYC and BCL2 and/or BCL6 Rearrangements (Version Date 09/28/21)

XXVI Continuing Review

S2015, Melanoma Margins Trial (MelMarT): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma (Version Date 12/22/21)

XXVII Continuing Review

EA2201, A Phase II Study of Neoadjuvant Nivolumab plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma (Version Date 08/18/23)

XXVIII Continuing Review

EA9213, A Phase II Study of Daratumumab-Hyaluronidase for Chemotherapy-Relapsed/Refractory Minimal Residual Disease (MRD) in T Cell Acute Lymphoblastic Leukemia (T-ALL) (Version Date 03/11/22)

XXIX Memos

E4A03, A Randomized Phase III Study of CC-5013 Plus Dexamethasone Versus CC-5013 Plus Low Dose Dexamethasone in Multiple Myeloma with Thalidomide Plus Dexamethasone Salvage Therapy for Non-Responders (Version Date 09/27/19)
