

Adult CIRB - Late Phase Emphasis Meeting Agenda

January 5, 2023

I New Study - Initial Review

EA7211, A Randomized Phase III Study of Neoadjuvant Chemotherapy followed by Surgery versus Surgery Alone for Patients with High Risk RetroPeritoneal Sarcoma (STRASS 2) (Version Date 11/30/22)

II Memos

S2104, Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors (Version Date 09/02/21)

III 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 10/11/22)

IV Continuing Review

A021806, A Phase III Trial of Perioperative versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer (Version Date 07/25/22)

V Continuing Review

A071601, Phase II Trial of BRAF/MEK Inhibitors in Papillary Craniopharyngiomas (Version Date 09/22/20)

VI Continuing Review

A151216, Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) (Version Date 09/07/21)

VII 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 06/16/22)

VIII Continuing Review

EA2205, A Randomized Phase II Trial Evaluating Chemotherapy vs Chemotherapy plus Bevacizumab and Atezolizumab in Advanced Combined Hepatocellular Carcinoma-Cholangiocarcinoma (Version Date 12/01/22)

IX 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 04/21/21)

X Continuing Review

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

XI Continuing Review

NRG-GI007, Phase I Trial with Expansion Cohort of OBP-301 (Telomelysin) and Definitive Chemoradiation for Patients with Locally Advanced Esophageal And Gastroesophageal Cancer Who are Not Candidates for Surgery (Version Date 01/11/22)

XII 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)

XIII 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 09/22/22)

XIV 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 09/30/22)

XV 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)

XVI 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)

XVII 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)

XVIII Continuing Review

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

XIX Continuing Review

S1512, A Phase II and Pilot Trial of PD-1 Blockade with Pembrolizumab (MK-3475) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM) (Version Date 03/21/22)

XX 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)

XXI 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 09/02/21)

XXII Continuing Review

S1826, A Phase III, Randomized Study of Nivolumab (Opdivo) plus AVD or Brentuximab Vedotin (Adcetris) plus AVD in Patients (Age \geq 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma (Version Date 04/02/21)



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XXIII 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)

XXIV Continuing Review

E1910, A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults (Version Date 12/03/19)
