

Adult CIRB - Late Phase Emphasis Meeting Agenda

February 3, 2022

I 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) (Protocol Version Date 10/15/21)

II Continuing Review

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

III Continuing Review

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

IV Continuing Review

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

V 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 (Protocol Version Date 12/13/21)

VI Continuing Review

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



VII Continuing Review

NRG-BR007, A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score ≤18 Breast Cancer (Protocol Version Date 03/05/21)

VIII 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) (Protocol Version Date 08/27/21)

IX Continuing Review

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

X 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 (Protocol Version Date 09/03/19)

XI Continuing Review

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

XII Continuing Review

S1512, A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM) (Protocol Version Date 10/15/21)



XIII 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 (Protocol Version Date 07/22/19)

XIV Continuing Review

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

XV Continuing Review

S1918, A Phase II/III Randomized Study of R-miniCHOP with or without CC-486 (Oral Azacitidine) in Patients 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 (Protocol Version Date 09/28/21)